3860

IRadimed CORPORATION

ADVANCED TECHNOLOGIES IN MR FLUID MANAGEMENT

MRidium™ MRI INFUSION/MONITOR SYSTEM

OPERATION MANUAL

REF 1138

MRidium™ 3860+ MRI Monitor/Infusion System

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General Information

This document provides the following directions for use:

- Single channel pump that provides a full range of features in a compact, easy to use, linear peristaltic pump.
- Dual channel pump offers the same features while providing two independent infusion pumps in one instrument.
- The Remote Display/Charger Unit allows for remote ability to control the Pump with a total of two channels from outside the MR Scanner.

The system is designed for use in the following patient care areas:

- MRI (0.2 to 3T systems).
- MRI/Recovery.
- Pump operable and safe in up to 1 Tesla (10,000 Gauss) magnetic field.

EMI Statement:

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: 1. Reorient or relocate the receiving device. 2. Increase the separation between the equipment. 3. Connect the equipment into an outlet on a circuit different from that which the other devices(s) are connected. 4. Consult the manufacture or field service technician for help.

Mains Disconnection Method:

3860 Pump: Disconnect power cord (1121) from Appliance Inlet on the side of the MRI power supply unit (1120).

3865 Remote/Charger Unit: Disconnect power cord (1128) from Appliance Inlet on the rear of the Unit.

Alternate Voltage/Export:

For power cord plug types see local country distributor. Unit shipped in USA with US 3 pin power NEMA plug.

3860 EQUIPMENT CLASSIFICATION	
Classification according to IEC 60601-1	
According to the type of protection against electrical shock:	Class I equipment and internally powered
According to the degree of protection against electrical shock:	Type CF (defibrillator-proof) equipment
According to the type of protection against harmful ingress of water:	Ordinary Equipment. Complies with Section 44.4 of the Infusion Pump standard, IEC 60601-2-24.
According to the methods of sterilization or disinfection:	Non-sterilizable. Use of liquid surface disinfects only.
According to the mode of operation	Continuous operation
Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	

About the Pump: Intended Uses

The Iradimed Corporation's MRidium 3860 MRI Infusion Pump/Monitoring System is intended for general hospital or clinical use by medical professionals whenever it is required to infuse patients with subcutaneous, intra-venous or intra-arterial fluids before, during, or after Magnetic Resonance Imaging (MRI) scans, functioning while either in a stationary or mobile position. The system is useful in the administration of fluids requiring precisely controlled infusion rates. The system can operate in either continuous, intermittent, or bolus delivery mode. The Infusion Pump can be used inside the MRI room mounted outside the 10,000 Gauss line (1 Tesla line), and with shielded magnets of field strength of 3.0 Tesla or less. This device is available for sale only upon the order of a physician or other related licensed medical professional, and not intended for any home use applications.

The Pulse Oximeter is used to measure, display, and record functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric, and infant patients in an MR environment. Testing of the oximeter was performed in MR conditional environments at 1.5T and 3T. It is indicated for spot checking and/or continuous monitoring of patients who are well or poorly perfused in the MRI.

The MRidium™ 3860 Infusion System incorporates a unique ultrasonic motor providing the non-magnetic motor power driving the MRidium™ 3860 pumping unit. This allows the MRidium™ 3860 to be constructed with minimal magnetic material and safely operable in high magnetic fields.

Features include:

- Non-magnetic ultrasonic drive motor.
- Special aluminum RF noise shielding enclosure.

The pump is equipped with a unique battery display that provides the clinician continuous monitoring of battery capacity available. This information is displayed when the instrument is turned on.

The Dual Rate Feature allows the pump to administer both primary and secondary solutions at separate flow rates and volumes. Using this feature the clinician can select and start a program for secondary delivery. Upon completion of the secondary dose, the pump can automatically switch over to a primary rate. Both channels of the MRidium™ 3860 can be programmed for primary and secondary operation.

Optional modes are easily accessed with the press of one key.

The Dose Rate Calculator allows the clinician to calculate a dose rate for continuous infusion given concentration and dosage orders.

The Bolus Dose feature allows the clinician to set up an initial infusion rate for a specific Bolus volume, automatically followed by a maintenance rate from the same container.

A 2.4 GHz wireless link allows communication between the infusion pump and remote display.

Qualified service personnel can configure many features of the pump to meet specialized needs.

Specific pump menu screens may vary depending on software release being used.

This device is covered under one or more of the following U.S. Patents:

7,267,661 B2, 7,404,809 B2 and International Equivalents

7,553,295, 7,553,882, 8,105,282 B2 and International Equivalents

Other U.S. and International patents pending.

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized infusion sets, sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

Masimo®, Masimo SET®, Signal Extraction Technology® and Signal IQ™ are trademarks or registered trademarks of Masimo Corporation.

Warnings/Precautions

Federal Law in the U.S.A. restricts this device to sale by or on the order of a physician.

This device is intended for use by trained medical professionals only.

Refer all service to Iradimed Corporation Authorized Service Representatives.

The 3860 Pump has been specifically designed for operation inside an MRI Magnet Room, and is designed to operate normally in the presence of most frequently encountered electromagnetic interference in the MRI environment. Under extreme levels of interference, such as in close proximity to an electrosurgical generator, cellular telephone or a 2 way radio normal pump operation may be interrupted. Avoid use of this pump under these conditions.

Use only MRI-compatible patient access devices (e.g. needles, luer-ports, etc.) to prevent any possible RF current from reaching the patient's skin.

The Remote Display Charger is intended for use in the MRI control room. Do not operate the 3865 Remote Display/Charger inside the MRI Magnet Room.

For safe operation, use only Iradimed Corporation recommended MRI-compatible or MRI-safe accessories.

The MRI pump must be mounted securely when used in the MRI scan room. Always securely mount the pump using it’s integral pole mount clamp or other mechanical fixing means.

Always secure the I.V. Pole wheel locks after positioning within the MRI Magnet Room.

Avoid placing the I.V. Set adjacent to any electrical conductor within the MRI bore, which can become heated during MRI scans.

The Alarm Sound Volume is adjustable for various clinical environments. Ensure the alarm sound level is appropriate for the use environment in the MRI so that it can be heard above the ambient noise level, especially during scanning.

Product damage may occur unless proper care is exercised during unpacking and installation. Do not use the pump if it appears damaged in any way. The battery should be charged before use.

Battery may not be fully charged upon receipt. Connect pump to AC power for at least nine (9) hours before placing the pump into use.

Always connect the infusion pump power supply or Remote Display/Charger to a properly grounded 3-wire power receptacle. If the quality of the earth grounding is in question, use battery power for the infusion pump.

This equipment is not suitable for use in the presence of flammable anesthetic or other gases. Do not use this system in the presences of flammable gases.

Arrange tubing, cords and cables to minimize the risk of patient or other equipment entanglement.

The pump is not intended for high pressure, high viscosity radiological contrast agents.

To avoid patient injury, always respond to Pump or Remote Display/Charger alarms immediately.

Never leave the patient with the Pump stopped if the infusion has not been completed.

To prevent injury, avoid placement of any NIBP cuff on the limb receiving the I.V. therapy.

The Pump contains materials which must be recycled, or disposed of properly. For proper disposal methods, contact your local sales representative or distributor.

Precautions (Continued)

Hospital personnel must ensure the compatibility of the drugs as well as the performance of each pump as part of the overall infusion. Potential hazards such as drug interactions, inaccurate delivery rates, inaccurate pressure alarms and nuisance alarms may arise from other incompatibilities.

MRI pump uses medical grade silicone rubber and PVC tubing. Do not infuse pharmaceuticals or solutions that are incompatible with these materials (for example, which contain diethylhexylphthalate (DEHP)).

Consult the drug labeling to confirm drug compatibility, concentration, delivery rates and volumes are suitable for concurrent delivery, or piggyback delivery (secondary followed automatically by primary).

Simultaneously infusing with more than one pump into one patient line may significantly affect the infusion rate of at least one of the pumps.

This infusion pump is contraindicated for use on the inlet side of Extra Corporeal Membrane Oxygenation (ECMO) systems or anywhere the negative pressure is greater than -100 mmHg as the high negative pressure can result in uncontrolled fluid flow.

Equipment use outside it's specified environmental conditions can affect infusion accuracy.

Pump Related Warnings/Precautions

This pump is designed to stop fluid flow under alarm conditions. Periodic patient monitoring must be performed to ensure the infusion is proceeding as expected.

Immediately respond to a "Close Door" alarm due to imminent lapse in infusion therapy.

Immediately respond to the "Check Door" alarm as this indicates possible Free-Flow of IV Fluids.

Dropping, or a severe shock to the pump, could result in damage and resultant pump inaccuracy. Refer the pump to qualified service personnel for proper checkout if either of these conditions occur.

Do not place the pump into use if it fails any of the Power On Self Tests.

Always verify flow rate, VTBI (Volume to be Infused) and/or dose drug entries before starting infusion.

When opening the door, always check that the free flow preventer (black slide clamp) is fully pulled outward to the shut off position.

If questionable Pump operation is observed, or if a System Failure occurs (i.e. an unexplained continuous audible alarm with no displayed values), discontinue use of the Pump and refer it to qualified service personnel.

Although unlikely, failure of certain rugged mechanical components, such as the free-flow prevention mechanism could cause fluid delivery limited to the contents of the fluid container. The maximum volume that may be infused under a *single fault condition* is 0.1 mL. Single fault failure of any electronic or motor control component would result in less than 0.3 mL of unexpected fluid delivery.

A small amount of fluid is expelled from the set (less than 0.05 mL) under worse case conditions when the mechanical drive advances to Index each time the pump latch is opened and closed with a set loaded. If potent drugs are being used, take appropriate action to guard against overmedication of the patient.

Always set the occlusion pressure alarm limit at the minimum level required for the prescribed fluid therapy.

Whenever closing the Pump Door, check to make sure that nothing interferes with the pumping mechanism.

During a running infusion, each interruption and re-start of the infusion can add approximately 0.05 mL of delivered fluid to the indicated Volume Infused.

Pump Related Warnings/Precautions (Continued)

There are dangerous voltages present on internal components that may cause severe shock or death upon contact. Never open the pump casing, it's power supply, or the Remote/Charger when connected to AC Mains power. Disconnect from AC power and remove battery pack prior to servicing or cleaning.

Do not operate the pump on patients with the battery removed (pump will stop and not alarm during AC power loss without battery installed). Use of a properly maintained and charged battery will allow proper operation. Do not touch battery connector pins and patient simultaneously.

If the Low Battery alarm sounds, connect the pump with its power supply to AC power immediately.

Replace blown fuses on the 1120 Pump MRI power supply or Remote Display/ Charger with fuses of the same type and rating only, or a fire hazard could exist.

Never use sharp objects (paper clips, needles, etc.) to clean any part of the pump.

Keep the pump door latch securely closed when the pump is not in use. This will avoid door latch damage.

Do not sterilize the pump or any component by heat, steam, ethylene oxide (ETO), or radiation.

The screen displays the VTBI (Volume to be Infused) in whole integers above 99.9. Any fraction of a milliliter delivered is not displayed, but is retained in memory.

To avoid damage to the I.V. Pump and Pole, always move the I.V. Pole separately from the patient trolley to prevent accidental entanglement.

The pump body is made of aluminum and is non-magnetic. However, when moving the pump within high magnetic fields (>2000 gauss) one might notice Eddy Current effects. These are forces generated in the aluminum which resists motion through the intense magnetic field. Such effects are normal and present no risk of free magnetic movement of the unit.

Set Related Warnings/Precautions

Always use aseptic techniques. Patient infection could result from mishandled or non-sterile assemblies.

Use only Iradimed Corporation MRidium™ 1000 Series administration sets. The use of other sets will cause improper pump operation resulting in inaccurate fluid delivery. MRidium™ 1000 Series administration sets are only intended to be used with the MRidium™ Pump.

All infusion administration sets are supplied sterile and are single use only. Do not sterilize or re-use.

Prior to use of any Infusion Set, examine the pouch and inspect for damage that could compromise sterility. If the pouch or Set is damaged, discard and use another Set.

Administration sets should be changed per the Center for Disease Control (CDC) guidelines or healthcare provider policy. Discard after use. Design use life of I.V. sets is six (6) hours maximum.

Disconnect the I.V. line from the patient before starting the priming procedure.

Prepare the primary solution container in accordance with the manufacturer's instructions.

The use of positive displacement infusion devices ported together with gravity flow infusion systems into a common I.V. site may impede the flow of the gravity flow system and affect their performance. Hospital personnel must ensure that the performance of the common I.V. site is satisfactory under these conditions.

Set Related Warnings/Precautions (Continued)

Interconnection with I.V. sets with small inner diameter may affect pump accuracy at high flow rates. Avoid interconnection with small bore diameter I.V. sets (less than 0.050 inch (1.25mm) I.V. tubing) if high flow rates are used.

A kinked or occluded I.V. line could cause the pump to operate abnormally and affect the accuracy of the infusion. Before operating this system, verify that the I.V. line is not kinked or occluded.

To avoid nuisance alarms, confirm that the fluid source is positioned higher than the pump.

Setting the primary rate greater than the secondary rate will result in a more rapid infusion of any residual secondary drug remaining in the line, the administration set, and fluid container.

When performing a secondary infusion:

- Secondary solution container must be higher than the primary solution container.
- The Secondary VTBI (Volume to be Infused) setting must be equal to the volume in the secondary container. This requires consideration of such variables as factory overfill, medication additions, etc. Underestimating the volume will cause the remaining secondary solution to be infused at the primary rate; overestimating will result in the primary solution being infused at the secondary rate. Multiple doses from a single container are not possible.

Air bubbles may form distal to the pump as a result of normal out-gassing of dissolved air in the fluid. This may occur if a chilled solution is being used, if the pump is mounted significantly above the patient, or with certain fluids known to routinely outgas. In these cases, an air eliminating filter may be required.

During a prolonged infusion, routinely inspect I.V. Set, access device and patient line assemblies for proper attachment and orientation.

Variations of head height, back pressure, selected catheter type, or any combination of these may affect rate accuracy. Factors that can influence back pressure are: I.V. set configuration, I.V. solution viscosity and I.V. solution temperature. Back pressure may also be affected by catheter type.

The use of pumping infusion devices ported together with gravity flow infusion systems into a common IV site (primary IV set with secondary IV lines) can affect the accuracy of the gravity flow systems, and result in unintended flow rates from these gravity systems. Always ensure the common IV site is acceptable for use under these conditions.

Reference to specific drugs and default parameters are provided for the user's convenience. Always refer to the specific drug product labeling for information concerning appropriate administration techniques and dosages.

Battery Pack Related Warnings/Precautions

The 1133 Battery Pack contains several lithium-polymer cells and an integral safety circuit. As these cells age, they can expand due to internal gas release, which is anticipated for this type of cell. However, if excessive expansion occurs, this can result in the battery case expanding (swelling), and possibly cause failure of the battery case, cells, or safety circuit. If this is observed, remove the Battery Pack from use and replace it as soon as possible.

The 1133 Battery Pack contains protective circuitry to prevent catastrophic battery failure. If the Battery pack is damaged, this protective circuitry may not prevent battery failure. Remove the Battery Pack from use if the Pack becomes damaged, or the potential for Battery Pack damage is suspected.

Do not use a damaged or swollen 1133 Battery Pack.

Avoid damage to the 1133 Battery Pack by impact, dropping, overheating, or mechanical abuse. Never compress, drop, shock, or strike the 1133 Battery Pack. Never use objects that could puncture the internal battery cells. Any of these actions can cause the battery cells to heat, smoke, or cause catastrophic battery failure, which could result in fire.

Do not attempt to disassemble the 1133 Battery Pack. Damage caused by disassembly or tool use can result in catastrophic battery failure, which could result in fire.

If the 1133 Battery Pack case begins to expand and/or swell, discontinue battery charging and use immediately, and replace the Battery Pack. Continued charging will cause further Battery Pack case expansion, with possible battery case fracture, and potential electrolyte leakage.

If the 1133 Battery Pack becomes damaged, avoid contact with the battery cell electrolyte. If the electrolyte contacts the skin or eyes, seek medical attention immediately.

If the 1133 Battery Pack shows sign of the battery case expanding (swelling), remove the Battery Pack from use and replace it as soon as possible. In extreme conditions, this swelling can cause the 1133 Battery Pack to become jammed or stuck within the 3860 Pump or 3865 Remote Display, and/or cause the Battery Pack plastic case to burst open. If this occurs, do not use tools that could cause damage to the internal battery cells. Refer to the 1125 Service Manual for removal under these conditions.

Under no circumstances should Battery Packs or the internal cells be incinerated as this can cause an explosion.

Pulse Oximeter Related Warnings/Precautions

USE ONLY Recommended SpO_2 Fiberoptic Sensors (Sensors containing electrical conductors will cause patient burns). Do not use cables or sensors that contain conductive wires.

This device is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

Iradimed SpO_2 sensors are reverse gender connectors (female connector on sensor cable / male connector on pump) than that found with other non-MRI pulse oximeters. This is done to help prevent improper sensor connection to the pump.

Use only recommended pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Iradimed Corporation's pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.

The fiberoptic cable for this device is extremely sensitive and must be handled with caution at all times. DO NOT use a damaged sensor.

Refer to the User Warnings and Precautions area in Section 7 (Pulse Oximeter) for additional Pulse Oximeter related warnings and precautions.

User Responsibility

This product will perform in conformity with the description contained in this users manual and accompanying labels, inserts, etc., when assembled, operated, maintained and repaired in accordance with the instructions provided. This product must be checked and calibrated periodically. A malfunctioning product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, refer unit to Iradimed Corporation qualified service personnel. This product or any of its parts should not be repaired other than in accordance with written instructions provided by the manufacturer, or altered without written approval of Iradimed Corporation. The user of the product has the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Iradimed Corporation or Iradimed Corporation authorized service personnel.

Using This Manual

Read this manual completely before attempting to use the pump.

Warning, Cautions and Notes. This manual contains three levels of precautionary information.

- A **Warning** alerts the user that there is a possibility of injury or death to a human being.
- A **Caution** alerts the user that there is a possibility of damage to equipment.
- A **Note** contains essential information deemed especially important by Iradimed Corporation.

Definitions

Channel A	The designation for the first infusion channel. All pumps contain at least one linear peristaltic pump head for one infusion line.
Channel B	The designation for the second infusion channel. The second infusion pump module is optional and some pumps may not contain it.
hr.	hour.
KVO	Keep-Vein-Open.
mL	milliliter.
Primary	Main Infusant for the prescribed I.V. therapy. The infusion settings that are implemented after any secondary infusion sequence is complete.
Rate	Infusion rate in mL / hr.
Secondary	The first infusion settings to be implemented in an infusion sequence. Sometimes referred to as “piggyback.”
VI	Volume Infused in mL.
VTBI	Volume To Be Infused in mL.
%SpO_2	Percent of Oxygen (pulse) Saturation.

Symbols

Attention: Consult Accompanying Documents, or alternately, Caution

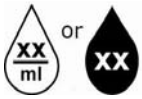
Defibrillator proof
Type CF Applied Part

Date of Manufacture

Indicates that the device conforms to the Medical Device Directive

Direct Current

Product is Latex-free



Drops per millimeter specification for I.V. Set is identified on Drop Symbol

Lot or batch code for I.V. Set will be identified near Lot Symbol

Approximate Set priming volume

Main Battery Capacity. (X inside Icon denotes no battery installed.)

AC Power is connected to 100-240 VAC

Secondary Infusion Mode

Volume to be Infused

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

Maximum rated load is 20 Kg.

Do not discard. Contact recycler for proper disposal

Appropriate for use in MR environment

MR Conditional. Only appropriate for use in MR environment with manufacturer's defined restrictions.

MR Unsafe. Not appropriate for use in MR environment (i.e. inside the MR magnet room)

Single Use Only

Product Serial Number

Alternating Current

Product does not contain DEHP in the fluid pathway

Product Part Number

Expiration date for I.V set will be identified near hour glass symbol

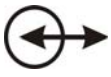
Denotes I.V. Set was sterilized with Irradiation

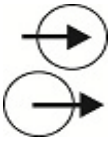
Contains Lithium. Requires proper disposal/recycling of this material.

Power On, or On

Power Off, or Off

Volume Infused


Both Input/output connection. Allows data communication.


Input Connection Only
Output Connection Only

EC REP — EC Authorized Representative

%SpO2 — Percent of Oxygen (pulse) Saturation

— Radio-Frequency transmission source

— Storage Temperature Range

This product has been certified to UL60601-1 and applicable Particular Standard IEC 60601-2-24, for which the product has been found to comply by Intertek.

No Lib	Indicates that the DERS Library is not active.
Lib	Indicates DERS Library is active and all settings are within the soft limits.
Lib +	Indicates the most recent over-ride was above the upper soft limit.
Lib −	Indicates the most recent over-ride was below the lower soft limits.
Lib	Indicates mutiple over-rides are active, but the most recent setting returned a value within both upper and lower soft limits.

— Refer to operating instructions for important safety informtion.

>>> — Alternating symbols indicate Channel A is infusing

— 2.4 GHz Radio is communicating.

BPM — Pulse Rate in Beats/Minute

— Pulse Detected

— Telecommunications Alert Symbol - Class 2 (European Union Countries Only)

— Spare Battery Capacity. (X inside Icon denotes no battery installed.)

— 2.4 GHz Radio Antenna

STBY — Infusion has been paused. Press start to resume infusion

<<< — Alternating symbols indicate Channel B is infusing

SECTION 1
INTRODUCTION

1.0 Introduction. The MRidium™ 3860/3860+ MRI Infusion/Monitor System is intended for patients that require medications and/or fluids during an MRI scan. This pump is designed to provide infusion therapy at all stages of the MRI procedure. This system is for use by trained medical personnel only and is not intended for long term patient care outside of an MRI environment.

This system provides the following features:

- Continuous Infusion, Dose Rate Calculation Program and Automatic Bolus.
- Automatic free-flow protection for the I.V. line.
- Up to two channel fluid delivery, each with separate primary/secondary programmable rate and VTBI, into single or separate IV lines.
- Rechargeable long life battery. Lasts up to 12 hours at 125 mL/hr.
- Status indicator light above door (Red for Alarm, Green for Infusing).
- Soft keys to program various functions.
- Large LCD display screen.
- Up and Down arrow control keys and 10 Key numeric Keypad to change numeric values quickly and easily.
- Handle for easy portability, weighs less than 11.5 pounds.
- I/O port for Service related functions.
- Optional second channel with the addition of the 3861 SideCar™.
- Optional remote control with the additional 3865 Remote Display/Charger.
- Optional Dose Error Reduction System with dedicated drug library card.
- Memory card slot for easy upgrades.
- On-Board Masimo SpO_2 Monitor (3860+ only).
- Expanded Infusion Rate Range from 0.1 to 1400 ML/Hr.

CAUTION: Handle the MRidium™ 3860/3860+ MRI Infusion/Monitor Pump and additional accessories with care. If it should be dropped or severely jarred, it should be immediately taken out of service and inspected by a qualified biomedical technician.

1.1 Product Description. The MRidium™ 3860 MRI Infusion/Monitor System is designed for operation in the MRI environment and may be used on the patient near the MRI magnet (up to the 1.0 Tesla or 10,000 Gauss Line). Operating on battery power, when fully charged this system will provide up to 12 hours of operation at an infusion rate of up to 125 mL/hr and at least four (4) hours at rates up to 999 mL/hr.

The MRidium Wireless Remote Display allows for remote ability to control the Model 3860 MRidium MRI Infusion/Monitor Pump with a total of two channels from outside the MR Scanner. It utilizes the same user interface as the 3860 infusion pump and will allow adjustment of all pump parameters, rates, titration, volume to be infused, starts, stops, and resetting alarms. The large clear display shows all pump information at your desk top from the control room. The Wireless remote also acts as a charger for a backup or spare battery pack for the 3860 MRidium MRI Infusion/ Monitor Pump. It utilizes a wireless link at 2.4 GHz for easy installation with no image artifacts.

NOTE: The 3860/3860+ pumps will only communicate with 3865 wireless Remote/Display units.

NOTE: The Remote Display/Charger only operates on AC Mains Power. This unit does not operate on battery power. This unit does not sound a Low Battery alarm for the Spare Battery being charged.

1.1.1 Front of the Pump. **See Figure 1-1** for the location of the major components on the front of the pump.

a. **Handle.** Located on the top of the pump, the handle provides for easy transportation of the pump from location to another.

b. **Main Display.** Provides a visual display of all the parameters and features of the pump.

c. **Run/Alarm Lamp.** Provides a visual display of the pumps operating condition.

d. **Battery.** Located behind a door on the back of the pump, the battery provides for power in the absence of a hospital grade AC Mains outlet.

e. **Pump Area EZ-Latch Door.** Pressing down on this button and lifting this handle unlatches the door protecting the pumping mechanism and infusion line.

f. **Main Control Keypad.** Provides control of the various features of the pump including 10 key numeric keypad for entering parameter values quickly and easily.

g. **Soft keys.** Provides a way to adjust the configuration of the pump.

h. **AC Power/Battery Charge LED.** Provides indication that MRI power supply is connected and AC power is applied to Charge the pump battery.

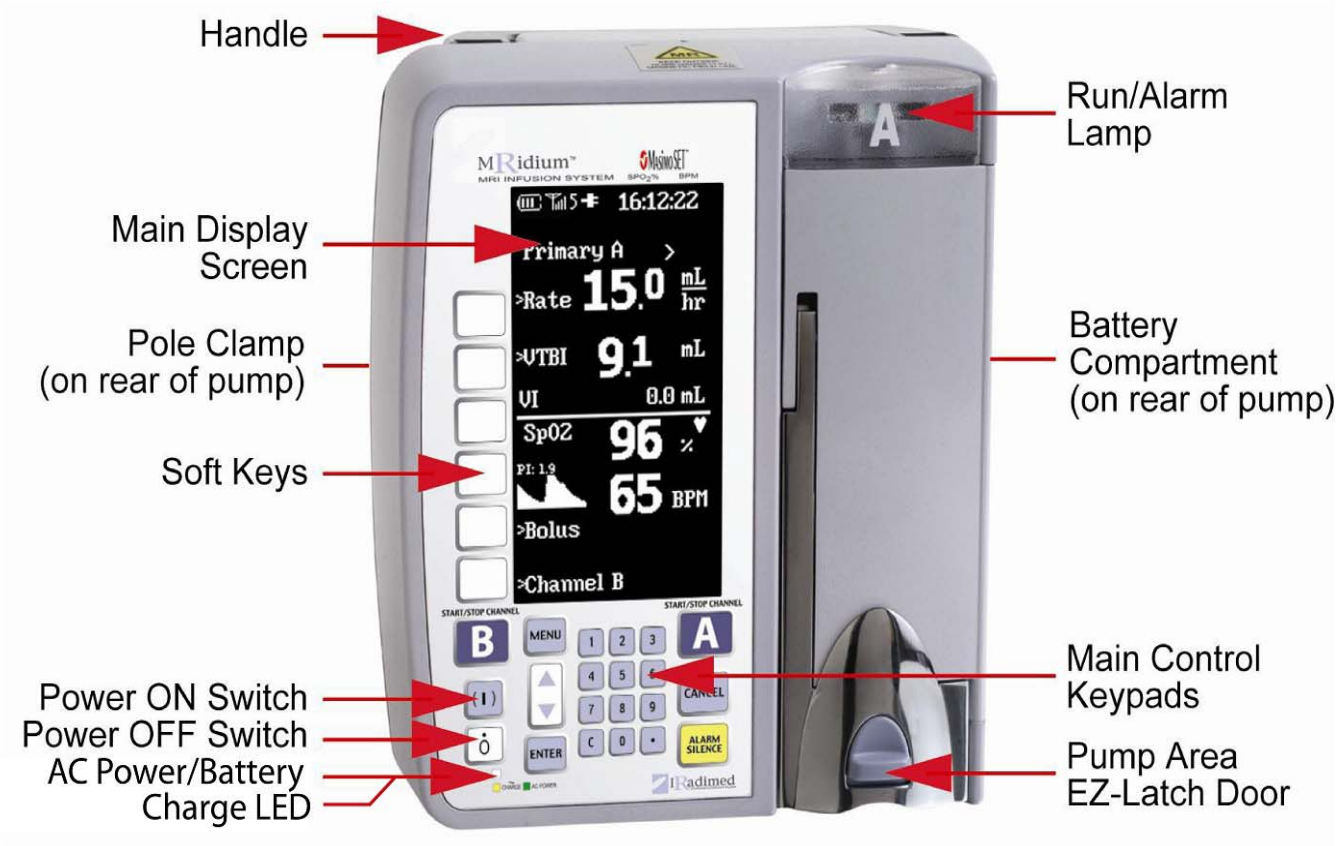


Figure 1-1. Front of Pump

1.1.2 Pump Drive Mechanism. **See Figure 1-2** for location of the major components of the infusion system pump drive mechanism.

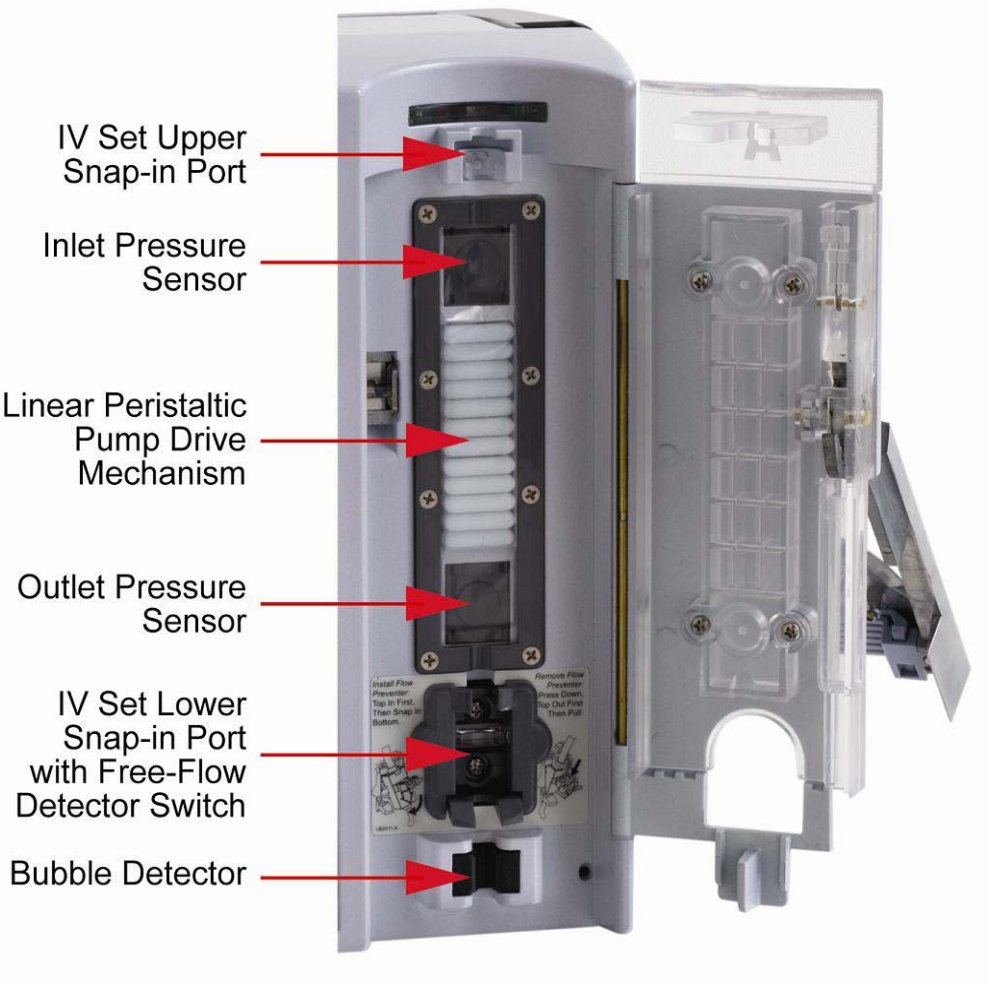

IV Set Upper Snap-in Port
Inlet Pressure Sensor
Linear Peristaltic Pump Drive Mechanism
Outlet Pressure Sensor
IV Set Lower Snap-in Port with Free-Flow Detector Switch
Bubble Detector

Figure 1-2. Pump Drive Door Open

a. **Upper and Lower I.V. Set Snap-In Port.** Provides for a secure mounting of the I.V. set for infusion.

b. **Linear Peristaltic Pump Drive Mechanism.** Provides for the positive movement of fluids through the infusion line.

c. **Bubble Detector.** Provides for the detection of air bubbles in the infusion line.

d. **Free-Flow Detector Switch.** Located internally in the pump's lower snap-in port the IV Set Free-Flow Detector Switch detects when IV set is properly installed and functioning.

e. **Inlet and Outlet Pressure Sensors.** Provide infusion line pressure measurements for pressure monitoring and alarms.

NOTE: After attachment of the 3861 Sidecar™ module (**Refer to Section 4.6**), the operation of Channel B Sidecar™ pump drive mechanism is identical to the main pump drive. The only difference is that the Channel B door opens to the left side, which is opposite that of the main pump door.

1.1.3 Back of the Pump. **See Figure 1-3** for the location of the major components on the back of the pump.

a. **Handle.** Provides for easy transportation of the pump from location to another.

b. **Optional Secondary Pump Drive Electrical Connector.** Provides for the addition of a Channel B pump mechanism.

c. **I.V. Pole Clamp.** Provides a secure mounting of the pump to the IV pole. Rotate knob clockwise to secure pump to the IV pole.

d. **Audible Speaker.** Provides the audible sounds for alarms and alerts.

e. **2.4 GHz Antenna and Connector.** Used to connect Antenna for Remote Display/Charger 2.4 GHz wireless interface.

f. **Power Input.** Provides for connection to the AC Power Adapter to run the pump on hospital grade AC Mains power. **Connect only model 1120 MRI Power Supply.**

Figure 1-3. Back of Pump

g. **I/O Port.** Provides a connection for retrieving the pump's infusion data from memory. **Connect only 60601-1 compliant computer for History Log download**.

WARNING: Serial I/O Port is not PC-compatible computer format (Pin # 8 is connected to the +5 volt supply). Refer to the Service Manual for History Log data download instructions. Do not communicate through this port during patient use.

h. **Memory Port.** Provides for field update of system software. **Use only AM04 update card or Iradimed Corporation recommended Media/Memory cards.**

i. **SpO_2 Sensor Port**. (3860+ only) Provides the connection for the Iradimed SpO_2 Fiber Optic Sensor. **Use only Iradimed model 1170 Series SpO_2 Fiberoptic Sensors.**

j. **Battery Compartment.** Provides a safe and secure location for the pump's battery. **Use only Iradimed model 1133 Battery Pack.**

CAUTION: Battery pack is slightly magnetic. Use caution when removing from pump near strong magnetic fields.

1.1.4 1120 MRI Power Supply. **See Figure 1-4** for information on the pump's MRI Power Supply.

WARNING: AC Adapter is magnetic. Keep outside the 1,000 Gauss line, or at least 10 feet (3 meter) from the MRI magnet. Secure with velcro straps provided to the floor. **NEVER** Velcro or secure the AC Adapter directly to the pump or I.V. pole.

Figure 1-4. Model 1120 MRI Power Supply

1.1.5 Front of the Remote Display/Charger. **See Figure 1-5** for the location of the major components on the front of the 3865 Remote Display/Charger.

a. **Antenna.** Provides 2.4 GHz bidirectional communication to MRidium™ 3860 MRI Infusion/Monitor Pump.

b. **Main Display.** Provides a visual display of all the parameters and features of the pump.

c. **Run/Alarm Lamp.** Provides a visual display of the pumps operating condition.

d. **Battery Charger Compartment.** Located at the top rear of the Remote, allows charging of an 1133 Pump Battery when battery is installed and Remote is connected to AC Mains outlet as indicated by AC Power/Battery Charge LED (located below the power On/Off keys).

e. **Main Control Keypad.** Provides control of the various features of the pump.

f. **Soft keys.** Provides a way to adjust the configuration of the pump.

g. **AC Power/Battery Charge LED.** Provides indication that AC power is applied (Green) or Charging a spare battery (Amber).

h. **Memory Port.** Located underneath the front panel provides for field update of system software. **Use only AM04 Software Card**.

Important: 3865 Remote Display/Charger will only communicate with 3860 or 3860+ pumps. These can be recognized by the 10 digit main control keypad.

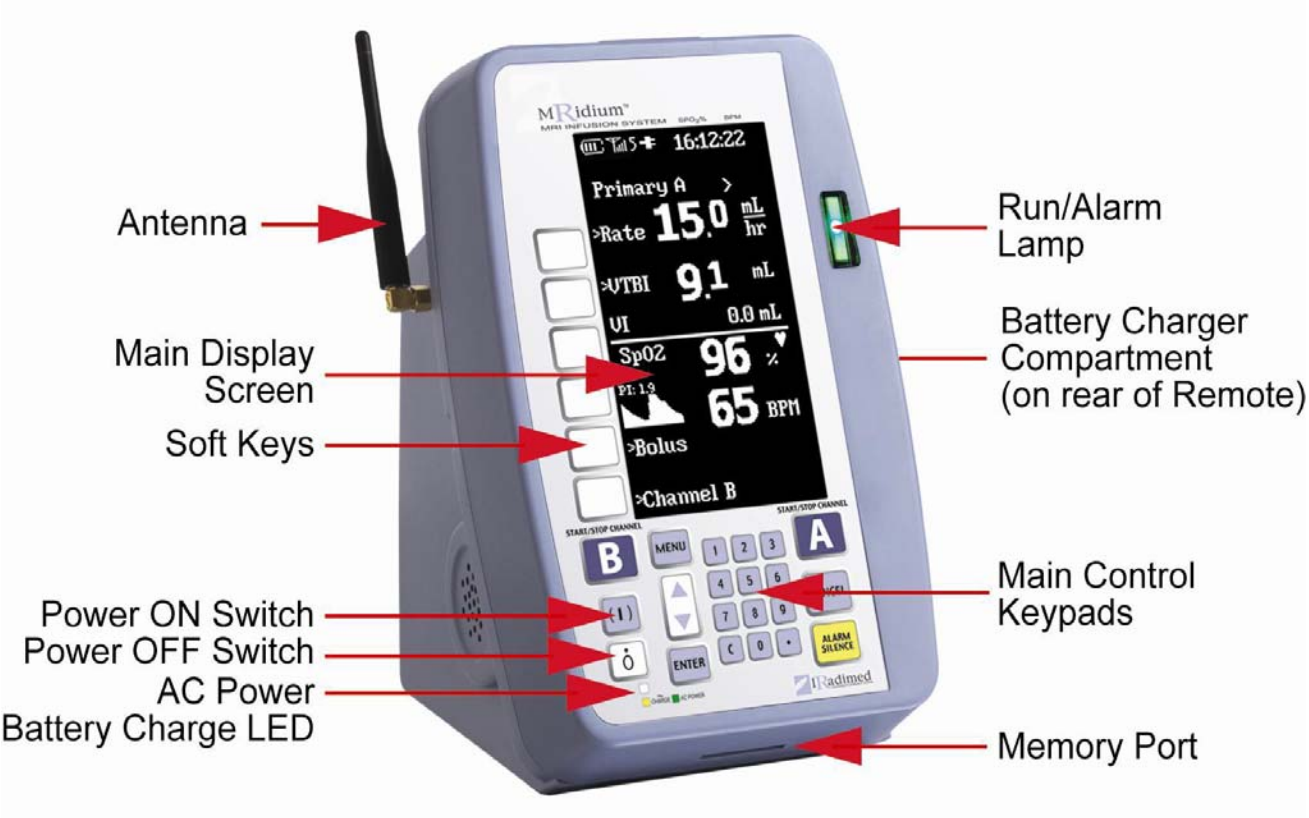


Figure 1-5. Front of 3865 Remote Display/Charger

1.1.6 Back of the Remote Display/Charger. **See Figure 1-6** for the location of the major components on the back of the 3865 Remote Display/Charger.

a. **Audible Speaker.** Provides the audible sounds for alarms and alerts.

b. **2.4 GHz Antenna / Connector.** Used to connect 2.4 GHz Antenna for wireless communication with the 3860/3860+ MR IV pump.

c. **Power Input.** Provides for connection to hospital grade AC Mains power.

d. **Fuse Holder.** Provides replaceable 1A 3AG, 250V fuse for the AC Mains power.

e. **Ground Terminal.** Used for grounding lug during electrical testing.

f. **Battery Charger Compartment**. Located at the top rear of the Remote, allows charging of an 1133 Pump Battery when battery is installed and Remote is connected to AC Mains outlet as indicated by AC Power/Battery Charge LED (located below the power On/Off keys). Remote/Charger is AC powered only and will not run on battery power.

CAUTION: Battery pack is slightly magnetic. Use caution when transferring battery pack from pump to Remote/Charger near strong magnetic fields.

CAUTION: Gently position 1133 battery pack into charger compartment until battery pack snaps into position. Do not drop or force the battery pack into the charger compartment, as this could cause battery pack damage or failure.

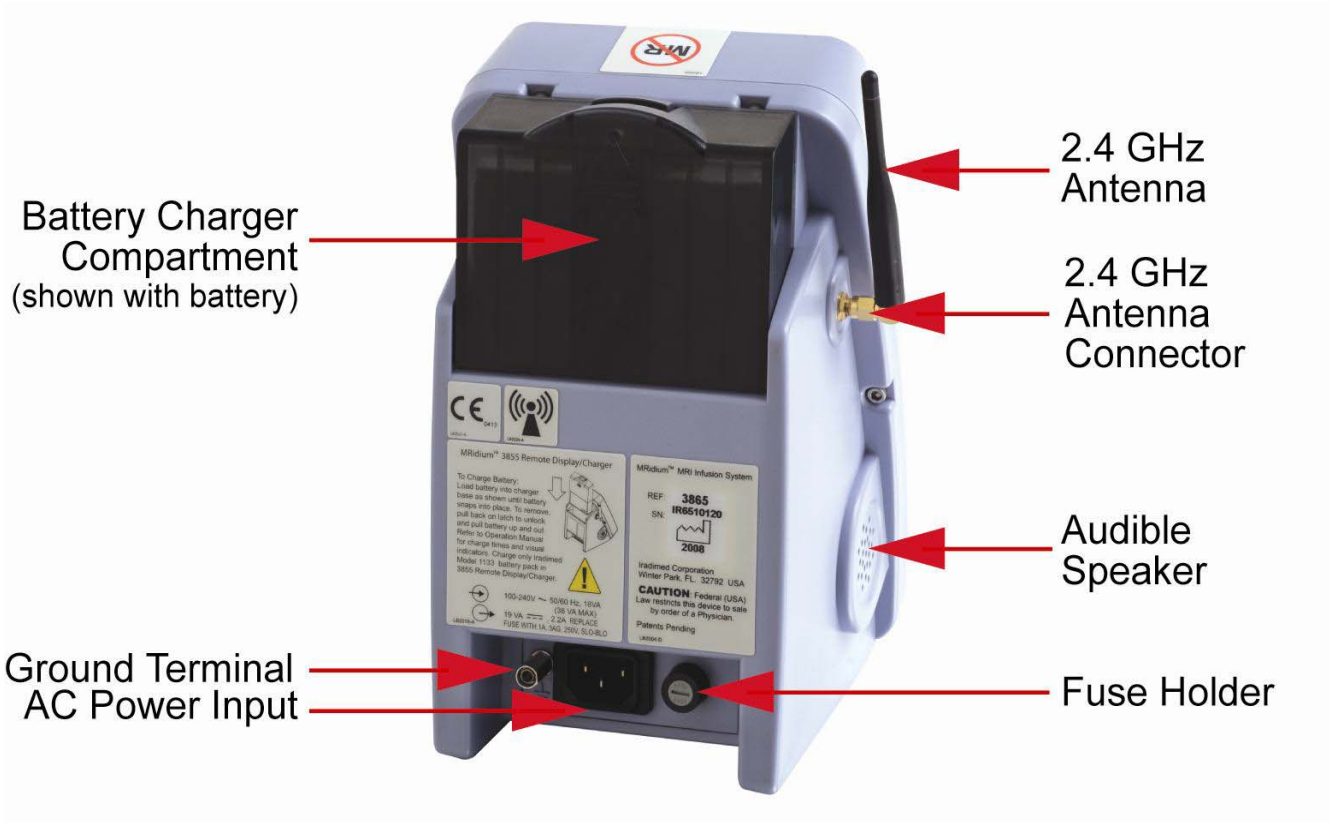


Figure 1-6. Back of 3865 Remote Display/Charger

1.2 Controls. The MRidium™ 3860 MRI Infusion/Monitor System is controlled with the use of "soft-touch" control keys. These control keys are located on the front panel of both the Pump and Remote Display. These control keys provide for turning the Pump and Remote Display ON or OFF, starting/stopping Channel's A and B infusion sequences, accessing and navigating in operational menus, review of data and setups, and for silencing any active alarms that may occur.

1.2.1 Front Panel Control Keys. **See Figure 1-7** for location of the control keys.

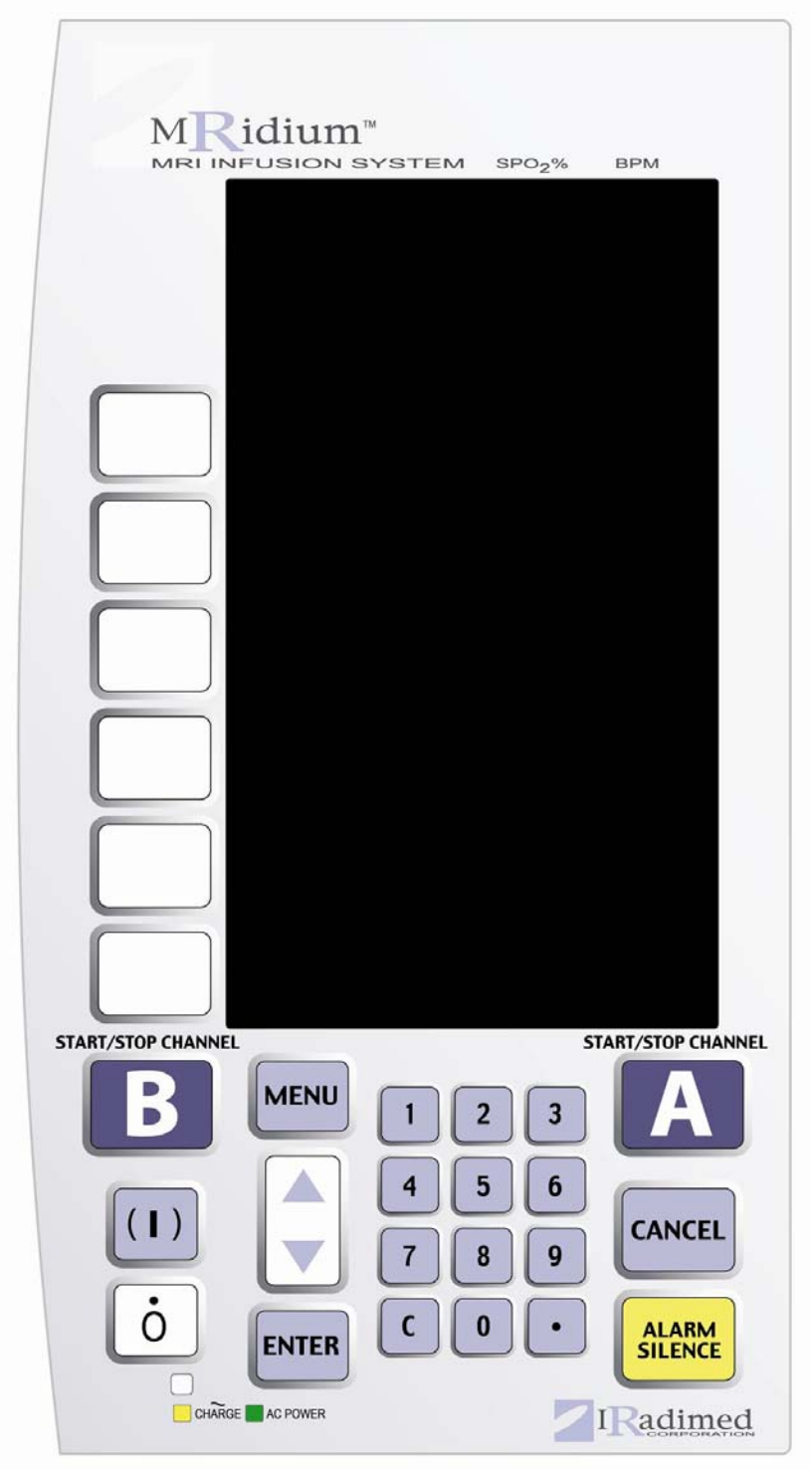
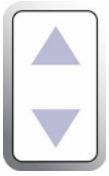


Figure 1-7. Front Panel Control Keys

START/STOP CHANNEL A. Pressing this control key starts, or stops, the Channel A infusion sequence.

CANCEL. Pressing the control key returns function to the previous menu or display with no action.



Up and Down Arrows. Pressing this control key will increase or decrease the value of the currently selected option. It is also used for on-screen menu navigation.

MENU. Pressing this control key activates the Main Menu Display.

ENTER. Pressing this control key will activate, or select, a menu choice, proceed from one prompt to the next and accept/ store changes.

START/STOP CHANNEL B. If the Channel B option (SideCar™ Pump mechanism) is installed, pressing this control key starts, or stops, the Channel B infusion sequence.

ALARM SILENCE. Pressing this control key temporarily silences audible alarms for two (2) minutes and clears alarms that have been resolved.

(I) Pressing this control key turns the unit on. When the unit is on this control key is inactive.

O Pressing and holding this control key for longer than one (1) second turns the unit off.

Special Function Soft Keys. The six (6) Soft Keys, located to the left of the pump's display screen, are used to perform variable functions depending on the current state of the device. When active there is a small arrow present to the right of the key on the pump's display.

Numeric Key Pad. The numeric keypad can be used to input values for flow rates or clear a recent entry ("C" key). After using keys to input correct values, pressing the "ENTER" key will lock value in place.

1.3 Display. The display screen provides the operator with the information and prompts necessary to operate this pump. **See Figure 1-8** for a description of the Primary display. In general, the display screen functions as follows:

- **Highlighting.** As the different settings are "scrolled" through (using the Up or Down arrow control key), the selected item will become highlighted to distinguish it from the unselected items.
- **Visual indicating of Soft key status.** Active Soft keys have a "arrow" beside them pointing toward the menu item or setting that the Soft key controls. When Soft keys are inactive, the "arrow" is not displayed.
- **Split Screen.** The pump displays different types of information in the same area of the screen no matter what particular display is active.

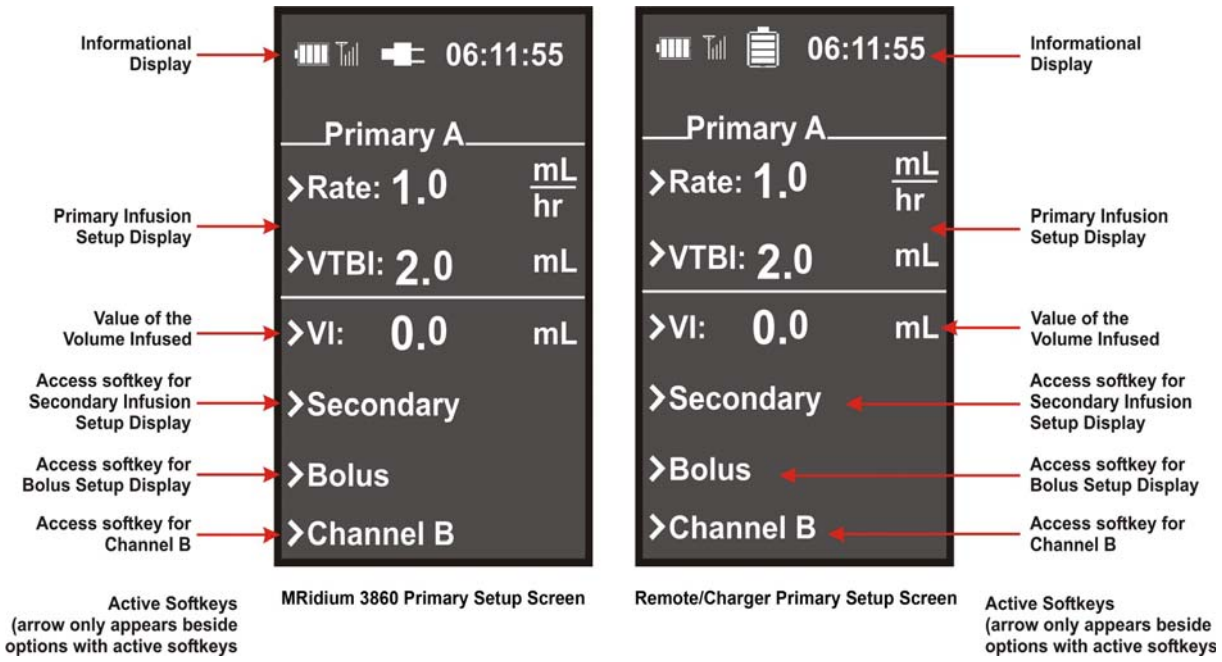
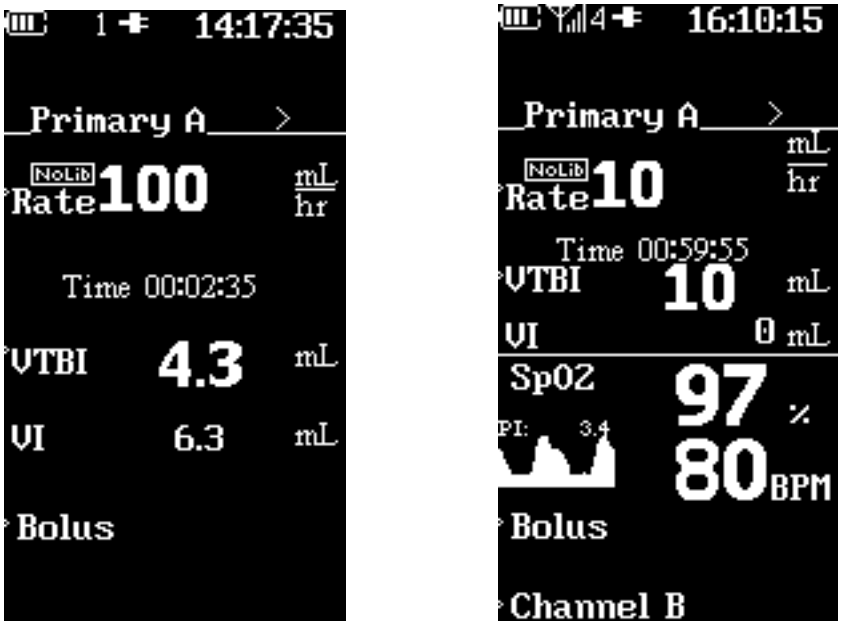
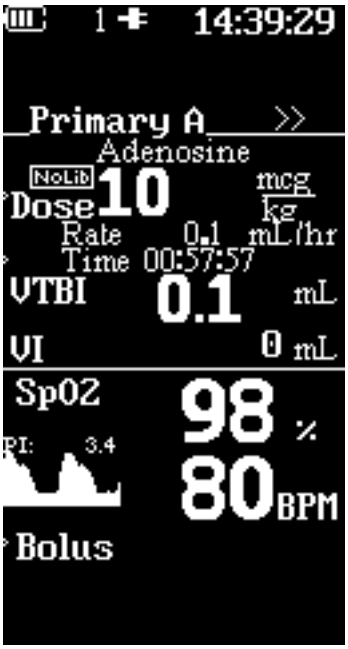


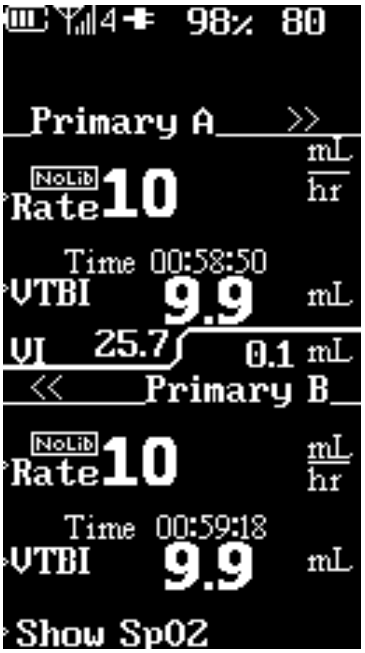
Figure 1-8. Setup Display Screens



Basic Running Screen Basic Running Screen with SpO_2



Running Screen using internal drug library and SpO_2



Dual Channel Running Screen

Figure 1-9. Running Screens

Additional information (i.e. Dose value, remaining Time, and Drug Library card use) can be displayed on the running screens with software revision 3.0.XXXX and higher.

1.3.1 Informational Display.The Informational Display is located at the top of the display screen. This portion of the display provides the operator with operational information such as the battery status, AC power status and the current time. *(Refer to Section 7 for MRI-SpO_2 related symbols and icons)*.

Provides a visual indication of the charge level of the Pump main battery. When full, the battery is charged fully. The level drops in increments of 25% on both the Pump and Remote as the battery discharges. If the symbol has an X through it no battery is installed.

Provides a visual indication of connection with Remote Display and receive level as indicated by vertical bars. Only displayed when internal radio has linked with Remote Display. Current channel is displayed to the right of the bars (1-6). **No bars indicates no communication**.

Provides a visual indication of the spare battery charge level in the Remote Display unit Informational Display. When full, the battery is charged fully. Level shows increments of 25% as the battery is charged, if symbol has an X through it no battery is installed.

Provides a visual indication that AC Main Power is connected on the Pump Informational Display.

06:11:55 Provides the current time in a 24 hour time format.

1.3.2 Infusion Parameter Setup Display. Below the informational display, the Infusion Display provides windows into which the Volume to be Infused (VTBI) and the Infusion Rate are entered.

1.3.3 VI Display. The VI Display provides the operator with the Volume Infused for the connected patient.

1.3.4 Secondary. Pressing this soft key brings up the Secondary Infusion Setup Display to provide the operator with the ability to configure a secondary infusion.

1.3.5 Bolus. Pressing this soft key brings up the Bolus Setup Display to provide the operator with the ability to configure a Bolus infusion.

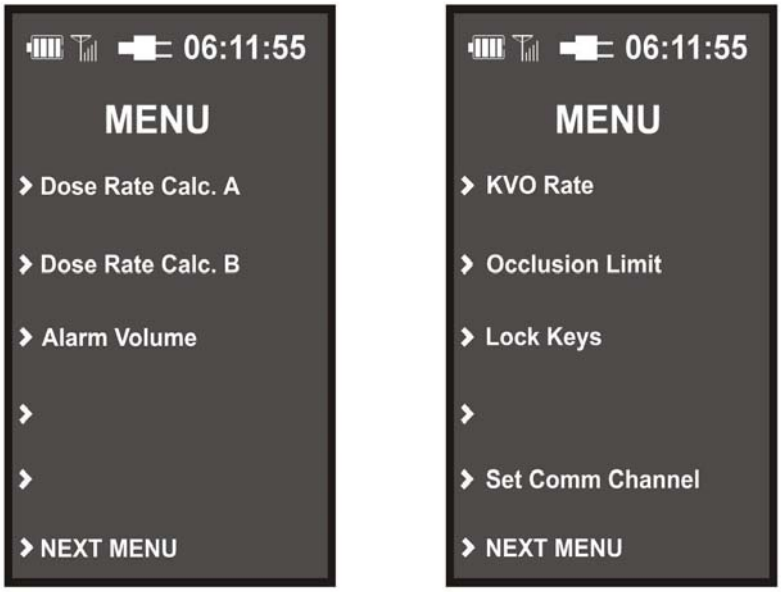


Figure 1-10. Special Features Setup Menu

1.3.6 Special Features Setup Menu. Pressing the MENU button brings up the Special Features Setup Menu (**See Figure 1-10**) to provide the operator with the ability to set the Dose Rate Calculation, adjust the Alarm Volume, set the KVO Rate, adjust the Occlusion Limit, and Lock Keys and Next Menu if additional options are installed. The Lock Key will not be displayed unless it has been enabled in the Service Mode. (Refer to 1125 Service Manual for additional details on the Service Mode.)

1.4 User Interface. The user communicates with the unit by pressing the appropriate control and/or soft key and then using the up or down arrows and enter control keys to set and verify the setting being made.

1.5 System Self Test. The unit performs a series of power on Self-Tests on start-up to confirm readiness for use. Failure during any of these Self-Tests will result in a fault message and inability to use the pump. Verify successful completion of self-test prior to each use.

1.6 Maintenance and Operator Verification. (Using IVP1056 IV Set). Verify Pump and Channel B SideCar operation on a routine basis. Maintenance and verification must be performed at least once/year.

Test Flow Accuracy: Flow pump output into a graduated cylinder with pump set at 200 mL/hr. Run pump for 12 minutes and verify volume is 40 mL +/- 5%.

Test Inlet Occlusion: With pump running 200 mL/hr close slide clamp on inlet side of pump and verify Inlet Occlusion Alarm.

Test Patient Occlusion: With pump running 200 mL/hr close roller clamp on patient side of pump and verify Patient Occlusion Alarm.

Test Bubble Detector: Insert a 100 uL bubble above the Bubble detector. Restart pump (ensure bubble flows down into detector), verify Bubble Detection Alarm.

Clean pump and inspect for any physical damage.

1.7 Cleaning Instructions. Clean Pump and Channel B SideCar and inspect for any physical damage after each use. Perform the following to clean the pump:

a. Unplug power cord from AC outlet before cleaning.

b. Remove Battery Pack from the rear of the Pump.

c. Do not spray fluid directly into any connector.

d. Use a soft cloth dampened with warm water and a mild, nonabrasive cleaning solution.

e. A soft-bristled brush may be used to clean narrow areas.

f. Use light pressure when cleaning pressure transducer and air-in-line detector areas of the pumping channels.

g. Acceptable cleaning solutions include (*use per manufacturers' instructions*)*:*

- Soap and Warm water
- Cidex® or other glutaraldehyde based surface disinfectants
- Quaternary ammonium compounds
- 10% Bleach Solution (1 part bleach to 9 parts water)

h. Refer to Section 7 for MRI-SpO_2 related cleaning instructions.

CAUTION: Do not use solvents or aromatic-solvent based cleaning agents. Damage to plastic parts of the Pump could occur. These include solutions containing aromatic solvents (naphtha, paint thinner, etc.), chlorinated solvents (Trichloroethane, Methy Ethyl Ketone (MEK), Toluene, etc.), alcohol, or phosphoric acid.

DO NOT use hard or pointed objects or pressurized sprays to clean any part of the Pump or Channel B SideCar.

DO NOT steam autoclave, EtO sterilize, or immerse the Pump or Channel B SideCar.

SECTION 2
INSTALLATION

2.0 Installation.

2.1 Introduction. This pump has been designed for the control and fluid management of patients undergoing magnetic resonance imaging.

2.2 Unpacking the Pump. Remove the pump and all accessories from their shipping carton and examine for visible damage that may have occurred during shipping. Check the materials carefully against the packing list and purchase request. Save all the packing materials, invoice and bill of lading as these may be required to process a claim against the carrier if there is damage from shipment. Contact Iradimed Corporation Customer Service for prompt assistance in resolving shipping problems.

The following is a list of items shipped with the pump:

- MRidium™ 3860/3860+ MRI IV Pump/Monitor.
- MRidium™ 1138 Operations Manual.
- MRidium™ 1139 Quick Guide Hang Tag Cards
- MRidium™ 1125 Service Manual CD*.
- MRidium™ 1133 Battery Pack for 3860/3860+ MRI IV Pump.
- Battery Charger/AC Adapter and Interconnect Cable.
- Hospital Grade Power Cord.
- One (1) Sample I.V. Set (Provided for initial Clinical Engineering testing).
- 2.4 GHz Antenna (for Wireless Remote)

***NOTE:** For Customer convenience, an electronic copy of this manual is included on the 1125 Service Manual CD-ROM provided with the pump.

NOTE: Customer must order MRI Infusion Sets and MRI SpO_2 sensor and accessories separately for use with this product (3860+ only).

2.3 Unpacking Remote Display/Charger. Remove the Remote/Display Charger and all accessories from their shipping carton and examine for visible damage that may have occurred during shipping. Check the materials carefully against the packing list and purchase request. Save all the packing materials, invoice and bill of lading as these may be required to process a claim against the carrier if there is damage from shipment. Contact Iradimed Corporation Customer Service for prompt assistance in resolving shipping problems.

The following is a list of items shipped with Remote Display/Charger:

- MRidium™ 3865 Remote Display/Charger.
- Spare Battery Pack (Optional).
- 1132 Installation Guide.
- Hospital Grade Power Cord.
- 2.4 GHz Antenna.
- LB2025 Channel ID Marker Sheet

2.4 Unpacking 3861 Channel B SideCar. Remove the Channel B SideCar from it's shipping carton and examine for visible damage that may have occurred during shipping. Check the materials carefully against the packing list and purchase request. Save all the packing materials, invoice and bill of lading as these may be required to process a claim against the carrier if there is damage from shipment. Contact Iradimed Corporation Customer Service for prompt assistance in resolving shipping problems.

The following is a list of items shipped with Channel B SideCar:

- MRidium™ 3861 Channel B SideCar.
- One (1) Sample I.V. Set (Provided for initial Clinical Engineering testing).
- 1131 Installation Guide

2.5 Preparing the Pump for Use. Once the pump has been unpacked, perform the following to prepare the pump for use.

2.5.1 Installing Battery. Slide the removable battery pack into the rectangular open slot on the rear of the MRidium™ 3860. The battery pack will lock into place.

a. **Battery Initial Charging.** The battery should be allowed to charge for nine (9) hours prior to placing the pump into use. The battery charges whenever the pump is connected to a hospital grade power outlet through the AC Power Adapter

2.5.2 Installing Optional Pulse Oximeter Sensor. Attach sensor to the SpO_2 port connector on the rear panel of the 3860+ I.V. Pump/Monitor. Grasp the SpO_2 sensor connector firmly and squeeze spring-loaded latches apart while attaching sensor to the SpO_2 port connector. Once the connector is attached, release the spring-loaded latches into the slots on either side of the connector to firmly secure SpO_2 sensor in place. Verify that the sensor is firmly connected to the port. Refer to Section 7 for additional information.

2.5.3 Removing The Pulse Oximeter Sensor. To remove the SpO_2 sensor, firmly grasp and squeeze the spring-loaded latches to release the latches while disconnecting the SpO_2 sensor from the pump.

CAUTION: Use only a non-magnetic I.V. pole designed for proper safe support of the MRidium 3860/3860+ I.V. pumps **(Iradimed model 1119 I.V. pole is recommended)**

2.6 Mounting on I.V. Pole. The Pump should be mounted on an MRI-compatible (non-magnetic) I.V. pole and secured with its ergonomically designed clamp knob. The clamping mechanism accommodates pole diameters 1 to 1.5 inches (25 to 38 mm).

WARNING: When using multiple Pumps (limit 2), distribute the Pumps to ensure stability.

2.7 Operational Checkout of the Pump. Power up pump as follows and confirm no failures are displayed during the Power Up Test.

a. Turn on pump.

b. Observe while pump performs power up test.

c. Verify that the pump sounds an audible beep.

d. Observe that the pump displays the initial start-up screen.

2.7.1 Determining the current IV Pump Software revision level:

1. Turn ON power to the MRidium™ 3860 or, re-start if power is already ON.

2. During the start-up sequence, the current IV Pump Software revision level is displayed in the upper part of the LCD display. The revision level, displayed as either REV: X.X.XXXX, or as “X.X.X”, directly below the words; “Powering On.” (X.X.XXXX, or X.X.X represents the software revision number).

2.8 Pump Storage. Plug the Pump into an AC outlet during storage to ensure a fully charged battery when needed. The AC indicator light will be green or amber (if charging) whenever Pump is plugged in to the AC Power. Close the door latch(es) whenever the Pump or Channel B SideCar are not in use.

2.9 Remote Display Installation. **See Paragraph 1.1.6**. Connect 2.4 GHz antenna and AC Power Cord to Remote Display/Charger. Verify MRidium™ 3860 MRI IV Pump has Remote Radio Option installed, and perform the following:

NOTE: Information shown on the Remote Display is updated at least once per second when communicating with the pump.

a. Turn both Pump and Remote Display/Charger on.

b. Press the Menu key on the Remote Display/Charger

c. See “NEXT MENU key” on page 4-22. Press the NEXT MENU soft key to bring up additional menu options, then press the Set Comm Channel soft key.

d. From the Radio Channel menu, select the desired Channel 1 through 6 by pressing the soft key next to that channel and verify that Channel is now highlighted.

e. Press the Menu key on the MRidium™ 3860 MRI IV Pump.

f. See “NEXT MENU key” on page 4-22. Press the NEXT MENU soft key to bring up additional menu options, then press the Set Comm Channel soft key.

g. From the Radio Channel menu, select the same Channel that was selected for the Remote by pressing the soft key next to that channel and verify that Channel is now highlighted.

h. Apply an ID marker to both the Remote and Pump indicating the Channel selected. Do not apply an ID Marker to the Channel B SideCar module as it can be removed to use on another pump.

i. Verify communication between Remote and Pump by pressing the Menu key on one and the Cancel key on the other, and observing both displays match and change simultaneously.

WARNING: Never Set two Pumps or two Remotes on the same Communication (Comm) Channel. Always confirm the Remote Display is communicating with the selected Pump before use.

j. Verifying communication between Remote and Pump (alternate method):

NOTE: With software version 3.0.1307 and higher, the Remote Display/Charger's communication channel can be linked with an operating 3860+ Pump without pausing the pump. At initial power on of the Remote Display/Charger, the start-up screen provides an option to select the communication channel of the Remote. To change the communication channel perform the following:

A.) Turn Remote Display/Charger on.

B.) The Remote Display/Charger display will show "Change Channel?" at the F5 key on the screen. This screen displays a count-down timer, that if no key is pressed in 5 seconds, normal operation will resume, and the communication channel will automatically be set to the previously selected channel when the Remote was last operated.

C.) During this 5 second count-down, the Remote Display/Charger display will also show "Use Channel X" at the F6 key on the screen (X represents the previously selected channel number when the Remote was last operated). If the F6 key is pressed, the Remote will display the Radio Channel menu screen.

D.) From the Radio Channel menu, select the desired Channel 1 through 6 by pressing the soft key next to that channel and verify that Channel is now highlighted. Press Enter to exit this screen and resume operation. The Remote will sound the synchronization tone sequence, and momentarily display "Synchronizing Communications" before the link is established.

E.) If the link is not established, press the NEXT MENU soft key to bring up additional menu options, then press the Set Comm Channel soft key to select the appropriate channel, as described above in steps 2.9.f and g.

F.) Once the communication link is established, verify communication between Remote and Pump by pressing the Menu key on one and the Cancel key on the other, and observing both displays match and change simultaneously.

2.9.1 Charging Battery with the Remote. If a spare battery is to be charged (**See Figure 1-6**), insert battery into the Remote Display/Charger's battery bay.

Verify spare battery Icon is visible on the Remote Display/Charger's informational display area. The AC/Power LED on the bottom, left-hand side will be amber colored until the battery is fully charged. The LED will turn green when battery is fully charged and the spare battery Icon in the Remote Display/Charger's informational display area will be full with 4 bars.

CAUTION: Gently position 1133 battery pack into charger compartment until battery pack snaps into position. Do not drop or force the battery pack into the charger compartment, as this could cause battery pack damage or failure.

NOTE: If communication between Remote and Pump is lost the Remote will sound a low pitched alarm for approximately 10 seconds. If communication is not returned after 10 seconds the Remote will sound a ramping high pitch alarm tone and display "No Communications."

2.10 Language Options. The MRidium System is capable of displaying information in languages other than English. This feature is service selectable, and should only be changed by qualified service personnel, as described in the 1125 Service Manual.

2.11 Product Structure. The MRidium 3860/3860+ MRI Infusion/Monitor system mainly consists of the following:

3865
Remote Display/Charger

3860/3860+
(Pump Main Body)

3861 (with 3860)
SideCar Pump

1170
SpO2 Fiberoptic Sensor

MRidium™ MRI Power Supply
MR
WARNING: KEEP OUTSIDE OF 1000 GAUSS (100mT) MAGNETIC FIELD LINE OR MORE THAN 10 FT. (3 M) FROM MRI MAGNET.
Iradimed Corporation
Made in USA

1120
Power Supply

1119
IV Pole Stand

SECTION 3
I.V. SET PREPARATION FOR USE

3.0 I.V. Set Preparation for Use.

Figure 3-1. Free Flow Preventer

(Free Flow Preventer is shown in the no flow/closed position).

a. **Operation of the Free Flow Preventer.** (**See Figure 3-1**) The Free Flow Preventer is used to stop the flow of the fluid through the infusion set. The Free Flow Preventer will open automatically to allow fluid flow when the pump door is shut and will also close automatically to prevent fluid flow when the pump door is open.

WARNING: To prevent free flow, verify Free Flow Preventer is in the closed position (slide clamp pulled out). When properly loaded in the pump, the Free Flow Preventer in the infusion set automatically prevents free flow when the pump door is opened. It can also be manually operated for user set-up convenience. The "CHECK DOOR" alarm indicates Free Flow Preventer is in the 'open' flowing position with the pump door not fully closed. Immediately check for proper IV set installation, Free Flow Preventer position, and pump door closure.

b. **Operation of the Roller and Slide Clamps.** Either the Roller Clamp (**See Figure 3-2a**), or the Slide Clamp (**See Figure 3-2b**), is the manual way used to stop the flow of the fluid through the infusion set. Close the Roller Clamp by moving the roller to pinch the tubing closed, or close the Slide Clamp by moving the clamp to pinch the tubing closed.

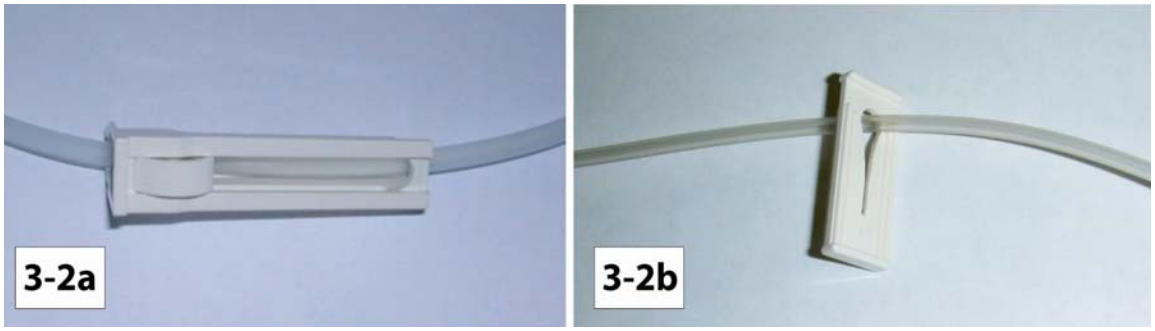


Figure 3-2. Roller and Slide Clamps

3.1 Precautions. The following precautions apply to the use of these I.V. Sets:

- Always use aseptic technique when handling any I.V. Set.
- The fluid path is sterile and nonpyrogenic, discard if packaging is not intact or if protector caps are missing or loose.

- Replace Set according to accepted hospital policies or every six (6) hours maximum.
- For I.V. push medication, occlude tubing above injection port.
- Contraindicated for most blunt cannula systems.
- For unattended medication delivery; only luer-locking Secondary sets and syringes should be attached to the valve.
- Flush injection ports in accordance with hospital policy after or between: small volume injections; lipids; blood or blood product infusions; blood withdrawals; incompatible medications.
- FREE FLOW-PREVENTER is OPEN when half-moon shaped clamp is pressed INWARD. To CLOSE, PULL the slide clamp OUTWARD.
- Dispose of used set in accordance with applicable regulations and hospital policy.
- Follow appropriate pump directions for use.

3.2 I.V. Set Priming. There are four I.V. Sets available for use with this pump. Priming of Administration Set 1056 is discussed in subparagraph 3.2.1; priming of ByPass Set 1055 is discussed in subparagraph 3.2.2; priming of Syringe Adapter Set 1057 is discussed in subparagraph 3.2.3. and priming of Extension Set 1058 is discussed in subparagraph 3.2.4. Always use aseptic technique.

3.2.1 I.V. Administration Set 1056 Priming. Refer to instructions accompanying the set. Perform the following to prime I.V. Administration Set 1056:

a. Remove from package, close roller clamp and remove blue tubing protector from silicone rubber pumping segment.

b. Insert administration set spike into prepared fluid container following accepted hospital procedure and hang fluid container approximately 15 inches above MRidium™ 3860 Pump.

c. Squeeze drip chamber to fill approximately 1/2 full.
   - Open vent cap if glass fluid container.

d. To prime tubing and clear air from injection sites, slowly open roller clamp, allowing fluid to fill tubing.

e. Invert and tap injection sites to clear any air bubbles.

f. Close roller clamp and Free Flow Preventer by sliding pinch clamp outward.

WARNING: Inlet Occlusion indication may not be reliable when used with bypassed I.V. sets that incorporate a check valve.

3.2.2 I.V. ByPass Set 1055 Priming. Refer to instructions accompanying the set. Perform the following to prime I.V. ByPass Set 1055:

a. **Ensure hospital pump set tubing is clamped closed**. Remove set from hospital pump.

b. Remove ByPass set from package, close roller clamp and remove blue tubing protector from silicone rubber pumping segment.

c. Attach clear covered Luer Lock connector to upper injection site on hospital set.

d. Open roller clamp on ByPass set, allow fluid to fill tubing.

e. Tap injection sites to clear any air bubbles.

f. Close roller clamp, close Free Flow Preventer pinch clamp by sliding it outward.

g. Attach blue capped Luer lock connector to lower injection site on hospital set.

3.2.3 I.V. Syringe Adapter Set 1057 Priming. Refer to instructions accompanying the set. Perform the following to prime I.V. Administration Set 1057:

NOTE: Do not puncture or add medication through air inlet (**See Figure 3-3f**).

a. Remove from package, close slide clamp and remove blue tubing protector from silicone rubber pumping segment.

b. Remove protective Clear Cap. Attach syringe with fluid to vented Syringe Adapter Fitting at top of I.V. set. Follow accepted hospital procedure. Ensure Tube Slide Clamp and FLOW-PREVENTER are open.

CAUTION: Do not place a stopcock between the syringe and the 1057 syringe adapter. an insecure connection can allow air to enter the line.

NOTE: When attaching syringe, ensure air vent tube is placed inside the syringe fluid path opening before luer-locking the syringe.

c. Manually push syringe to prime I.V. Set removing all air bubbles.

d. Open air vent cap on Syringe Adapter Fitting (**See Figure 3-3**.)

e. Close slide clamp, and close FLOW-PREVENTER by sliding black pinch clamp outward.

f. Grasp FLOW-PREVENTER slide clamp and load pump segment into Pump.

g. Close Pump Door. Ensure syringe with fluid is mounted vertically after set is loaded and Door is closed.

h. Attach distal luer-outlet (White cap) to the port nearest the patient's vascular access device.

i. Open set slideclamp and begin infusion.

CAUTION: Do not strike or jar the syringe adapter it has been loaded onto the 1057 Syringe Adapter Set and mounted onto the pump. I.V. set or syringe damage could occur.

NOTE: Small diameter tubing (0.040 inch) is used in the 1057 Set. Dependent on the desired Flow Rate and fluid viscosity, the Pump's Occlusion Pressure Limit may need adjustment to avoid false alarms. Pressures may exceed the maximum allowable limit for Flow Rates above 600 mL/hr.

Do NOT depress the syringe plunger during infusion. Fluid leakage out the air inlet can occur. Since this set is vented, fluid will flow without movement of the syringe plunger. If the patient's access device requires needle access, add a 17 Gauge (or larger) needle to the 1057 set's luer-outlet before attaching to the access device.

3.2.4 I.V. Extension Set 1058 Priming. Refer to instructions accompanying the set. Perform the following to prime I.V. Extension Set 1058:

a. **Ensure hospital pump set tubing is clamped closed.** Remove pre-existing infusion set from its non-MRI hospital pump. Ensure flow is stopped/clamped-closed before removal.

b. Remove 1058 Extension set from package, close both the roller clamp and FLOW PREVENTER and remove blue tubing protector from silicone rubber pumping segment.

c. Attach inlet luer-fitting (clear cap) to the pre-existing infusion set at its distal end.

d. Open roller set clamp to prime the set. Ensure FLOW PREVENTER is open.

e. To remove air from the injection port, invert and tap while fluid is passing through the port.

f. Close FLOW PREVENTER pinch clamp by pulling the black slide clamp outward.

g. Grasp FLOW PREVENTER slide clamp and load pump segment into MRidium pump.

h. Attach distal luer-outlet (blue cap) to pre-existing infusion set's injection port nearest the patient's vascular access device.

i. Open set roller clamp and begin infusion.

3.3 I.V. Set Insertion and Removal. For insertion instructions see subparagraph 3.3.1 and for removal instructions see subparagraph 3.3.2.

WARNING: DO NOT STRETCH the silicone rubber segment of the I.V. Set. When properly loaded, the silicone rubber segment should be taut (without slack) and centered atop the pump's peristaltic "fingers", as shown in **Figure 3-3**, page 3-5. Overstretching, or mis-positioning of this tubing can result in inaccurate flow, and/or free-flow.

WARNING: Confirm that the I.V. Set is fully primed prior to inserting the set into the pump.

3.3.1 Administration Set Insertion. Perform the following to insert the Administration set into the pump: (**See Figure 3-3**)

a. Press the ON Control Key (I).

b. Open MRidium™ 3860 Pump door.

c. Install administration set pumping segment by properly positioning the upper tubing retainer (see Figure 3-3a) and ensure Free Flow Preventer is closed (see Figure 3-3b).

DO NOT STRETCH TUBING

d. To insert the Free Flow Preventer, tilt the Free Flow Preventer, top in first (see Figure 3-3c), and rotate bottom downward to lock into place using Free Flow Preventer's slide clamp. Assure tubing above Flow Preventer is located directly down the middle of white PUMP "fingers" (see Figure 3-3g).

e. Run tubing through the Air-in-Line detector (see Figure 3-3d) at the bottom of the pump.

f. Close MRidium™ 3860 Pump door.

g. Open roller clamp, or slide clamp, depending on IV set type.

h. Verify no flow is flowing through the drip chamber (1055, 1056, or 1058 type IV Sets), or if using 1057 syringe set, be sure to open vent cap prior to starting pump (see Figure 3-3e-f).

3.3.2 Administration Set Removal. Perform the following to remove the Administration set from the pump:

a. Press the START/STOP Channel control key on the MRidium™ 3860 Pump

b. Close the roller clamp

c. Open the MRidium™ 3860 Pump door, which automatically closes the Free Flow Preventer

d. Remove the tubing by grasping the Free Flow Preventer by the Slide Clamp and push down while tipping the top outward.

The tubing will allow gravity flow when the Free Flow Preventer pinch clamp and the roller clamps are in the open position. This provides the ability to infuse fluids/ medications via gravity in an emergency situation.

WARNING: Check Free Flow Preventer (black side clamp) is fully pulled outward to the shut off position.

CAUTION: Check Free Flow Preventer (black side clamp) is fully pulled outward (shut off) any time the chamber door is not fully latched in the closed position. Partial closure of the door may open the Free Flow Preventer, always close door and fully latch.

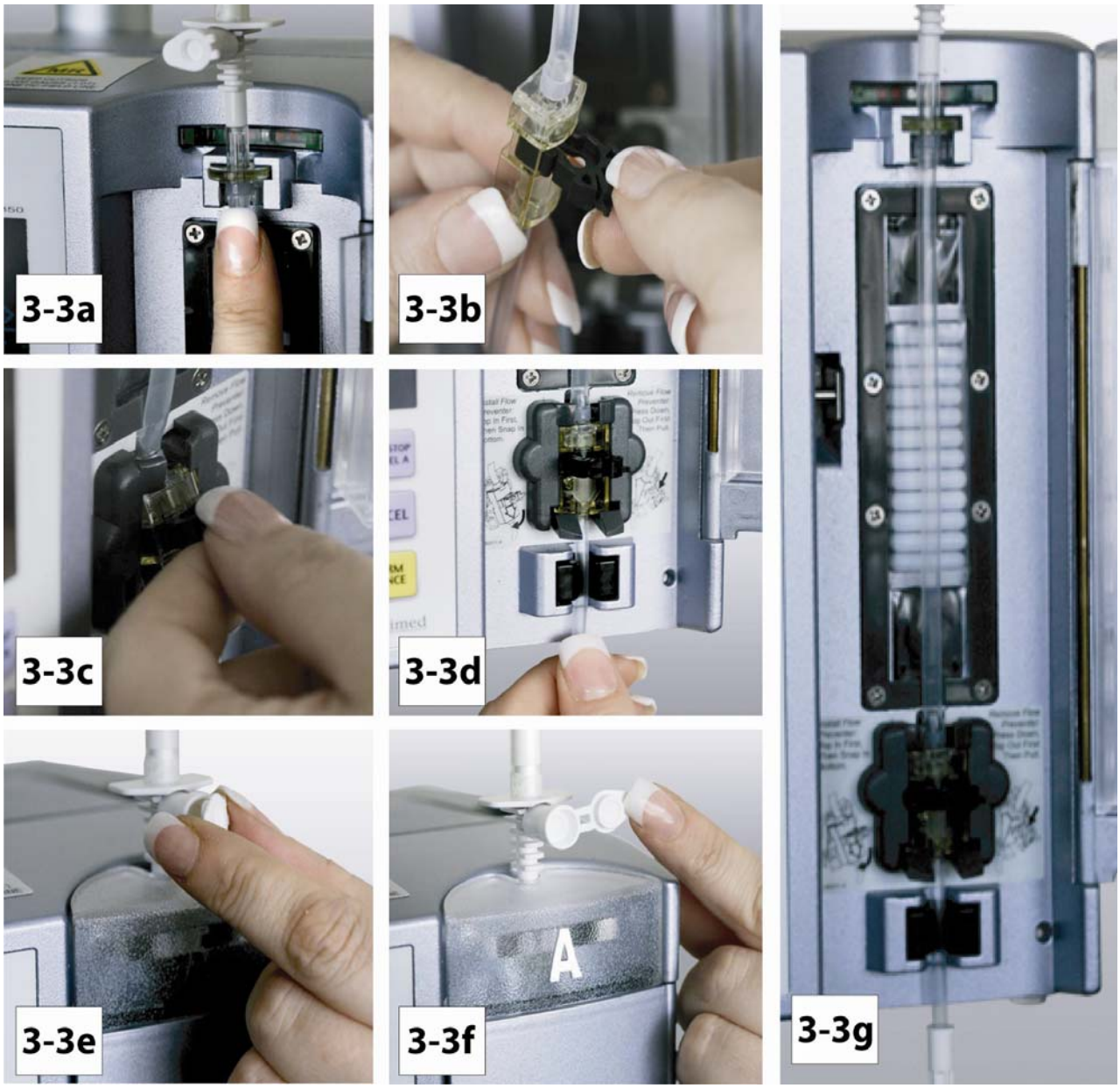


Figure 3-3. IV Set Installation

SECTION 4
PUMP PREPARATION FOR USE

4.0 Pump Preparation for Use.

4.1 Quick Setup. Perform the following to setup the pump:

Press the (I) control key to power on the MRidium™ 3860 Infusion Pump.

a. If displayed, select “Same Patient” to use the last infusion settings or “New Patient” for new dose information. This menu will not be displayed if pump is off for more than one (1) hour.

b. Adjust Rate using the numeric keypad or the Up and Down arrow keys, then press the ENTER control key.

c. Adjust VTBI using the numeric keypad or Up and Down arrow keys, then press the ENTER control key.

d. Open I.V. Set Compartment door and install primed and de-bubbled MRidium™ 1000 Series I.V. Set. Take care that the Black Free Flow Preventer tab is pulled outward.

e. Shut the I.V. Set Compartment door and press the Start/Stop control key for the desired pump channel when the “Ready to Start” message appears.

f. Monitor pump is correctly delivering I.V. therapy by viewing the green blinking light above the selected channel. Check fluid drip rate in the drip chamber.

WARNING: This pump will stop fluid flow during Alarm Conditions, however, SpO_2 related alarms will not stop fluid flow. Periodic patient monitoring must be performed to ensure that the infusion is operating normally.

WARNING: It is the responsibility of hospital personnel to ensure that drugs used in this system are compatible as well as ensuring the performance of each pump as part of the overall infusion. Potential hazards include, but are not limited to, drug interactions, inaccurate delivery rates, inaccurate pressure alarms and nuisance alarms.

WARNING: The use of positive displacement infusion devices connected together with gravity flow infusion systems into a common I.V. site may impede the flow of common “gravity only” systems and affect their performance. It is the responsibility of hospital personnel to ensure that the performance of the common I.V. site is acceptable under the circumstances in which it is being used.

4.1.1 Administration Sets. Use only Iradimed Corporation approved MRidium™ 1000 series infusion sets. The use of any other set will cause improper pump operation and will result in inaccurate fluid delivery and risk to the patient.

Before beginning any infusion cycle, verify that the infusion lines are free from kinks and are loaded correctly on the pump.

Do not reuse any component that is labeled for single use. Discard these items immediately after use.

4.1.2 Artifacts. It is normal for this pump to produce non-hazardous currents when being used for the infusion of electrolytes. These currents will vary proportional to the pump's infusion rate. Therefore, when an ECG monitoring system is not functioning under optimal conditions, these currents may appear on the ECG display screen as artifacts and simulate actual ECG readings. To determine if the ECG abnormalities are caused by patient condition or the ECG equipment receiving artifact from the pump, place the infusion pump on HOLD and observe the ECG signal. If the ECG signal becomes normal, the ECG monitor requires attention as proper setup of the ECG equipment should remove the pump caused artifact. Reference the appropriate ECG monitoring system documentation for instructions on setup and maintenance of the ECG device.

NOTE: Operating parameters (Power, VTBI, etc.) are retained in memory for one (1) hour unless all power is lost (no AC and a depleted battery). A "Settings Lost" message at power up indicates existing operating parameters have been erased, and the system has reverted back to initial default parameter settings.

The operator may choose "New Patient" or "Same Patient." Same patient will pre-set primary pump setup display with the prior Rate and VTBI. New patient will clear the Rate, VTBI and VI.

If the Primary Pump Setup screen does not appear as shown in Figure 4-1, it may indicate improper functioning of the display. Although the Pump may appear to function properly, return it to qualified service personnel for examination and/or repair.

CAUTION: Each time the Pump is turned on, verify and/or set the pressure alarm limit. If the pressure alarm limit is not verified, the Pump may not be operating with the desired occlusion detection parameter(s).

4.2 Primary Configuration. Pressing the control key powers up the pump. Upon power up the pump first runs a Power On Self-Test then displays the message "Powering On" and enters the Primary Pump Setup screen (**See Figure 4-1**) where the Infusion Rate and Volume to be Infused (VTBI) is set.

The pump memory will retain the last used settings for up to one (1) hour following power down of the pump). Operator has the option of selecting either "New Patient" or "Same Patient."

If any part of the Power On Self-Test fails, the pump displays an error message and will not operate.

If optional Channel B SideCar is installed on the left side of the display, the user may select and program Channel B in the same manner as Channel A by selecting the Channel B softkey.

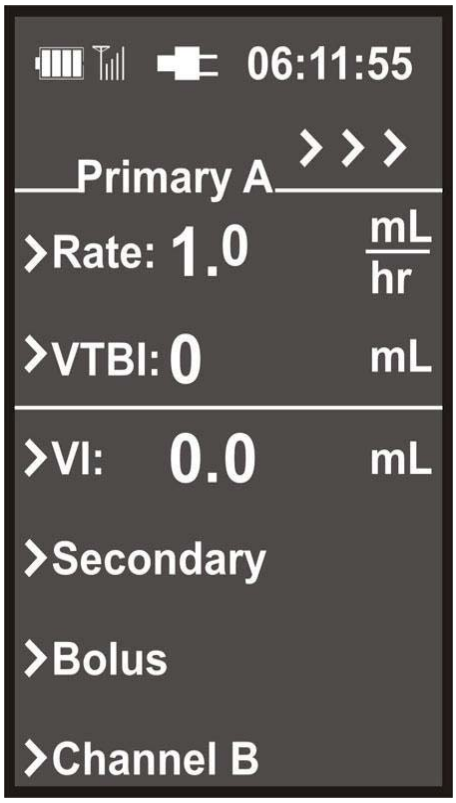


Figure 4-1. Primary Pump Setup Screen

4.2.1 Programming a Basic Infusion. Perform the following to enter the primary Rate and VTBI for infusion:

a. Insert primed MRidium™ 3860 I.V. Set into pump and close door.

b. Observe that the RATE value is highlighted (if not highlighted, select using the soft key to the left of Rate).

c. Press the numeric keys (or the up and down arrow keys) to enter the desired flow rate.

d. Press ENTER or VTBI soft key to move to the next field.

e. Observe that the VTBI value is highlighted.

f. Use the numeric keys (or the up and down arrow keys) to enter the desired volume to be infused.

g. Observe that the Ready to Start Prompt is displayed. If Ready to Start is not displayed, check the I.V. Set loading and for proper door closure/ latching.

NOTE: The VTBI is displayed on the main display screen of the MRidium™ 3860 pump and will count backwards to 0 mL. At that time the infusion rate will change to the predetermined KVO rate, and the VTBI will display KVO rate.

h. Press the START/STOP (A or B) Channel control key for the proper Channel to begin the infusion.

i. Observe that the rate and VTBI are displayed and the green infusing indicator is flashing.

j. Verify infusion is running from primary container by observing the drip chamber, or air bubbles within the loaded syringe (1057 Set only).

NOTE: The Pump needs to be ON prior to loading the I.V. Set. If tubing is installed prior to turning Pump on, “Load Set” or “Unload Set” messages may appear. Remove and replace I.V. Set to clear. “Ready to Start” prompt will appear.

4.2.2 Editing the Infusion Program. The clinician has the ability to change or edit (titrate) the infusion program without having to pause the infusion. Perform the following to change or edit the infusion program:

a. Press the RATE or VTBI soft key and set the new parameter(s) using the numeric keys (or the up and down arrow keys).

b. Press ENTER to accept the new value.

NOTE: While the pump is in use, all infusion parameters are stored in memory unless the pump has been powered down for more than one (1) hour.

NOTE: If the original VTBI and any additional titrated volume exceeds the maximum VTBI (999 mL), when the “Same Patient” option is selected for subsequent infusion, the VTBI will be reset to zero (0) to prompt the user to select a new VTBI.

NOTE: With very low infusion rates (i.e. <1.0 mL/hr), timed doses may adjust displayed time due to rounding of calculated values. Infusion will be delivered using displayed Rate and VTBI, and recalculated time is adjusted accordingly.

4.2.3 Canceling/Pausing an Infusion. The clinician has the ability to pause an infusion by pressing the START/STOP Channel control key (for the channel to be cancelled/paused) once. When the START/STOP Channel control key has been pressed, the pump will display CANCEL INFUSION next to a soft key and the indicator light will go out. Every 15 seconds, the pump will give a periodic audible tone to remind the operator that the pump is still on hold (unless the reminder beep has been set to “OFF” in the service mode). When the infusion is paused, “STBY” symbol is displayed adjacent to the paused channel.

a. To cancel the infusion, press the soft key next to the CANCEL INFUSION message.

b. To restart the infusion, press the START/STOP Channel control key for the channel to be restarted.

4.2.4 KVO (Keep Vein Open) - Infusion Complete. During an infusion, the VTBI value will decrease until the VTBI reaches 0 mL. When the VTBI is 0 mL, the infusion automatically switches to the configured KVO rate, or remains at the programmed primary flow rate, whichever is less. KVO is displayed next to the VTBI and the RATE will display either the preselected KVO rate or the current infusion rate (again, whichever is less). A short tone will announce the switch to KVO. The KVO rate is configurable from the Special Features Menu (which is accessed by pressing the MENU control key) and has a rate range from 0 mL/hr to 5 mL/hr.

NOTE: When the KVO rate is set to 0 (off), and the infusion is complete, the short tone will occur, and the infusion will stop. As with a paused infusion, the pump will give a periodic audible tone every 15 seconds to remind the operator that the pump is not infusing (unless the reminder beep has been set to “OFF” in the service mode). When the infusion is paused, “STBY” symbol is displayed adjacent to the paused channel.To continue, press the “CANCEL” key to access the set-up screen.

a. **Resuming an Infusion after KVO.** Perform the following to resume an infusion after KVO has initiated:

(1) Press the START/STOP Channel control key.

(2) Replace infusion bag/bottle.

(3) Press the VTBI soft key.

(4) Observe that the VTBI value is highlighted.

(5) Use the numeric keys (or the up and down arrow keys) to enter the new volume.

(6) Observe that the Ready to Start prompt is displayed.

(7) Press the START/STOP Channel control key to resume infusion at the prior rate.

4.2.5 Volume Infused. The MRidium™ 3860 pump tracks the Volume Infused (VI) when the device is used to deliver fluid to the patient. The VI on the device is cumulative with the system calculating the total VI including both the primary and secondary infusions. The operator has the ability to clear the VI for a specific channel or for all attached channels from the setup screen only. The VI is displayed on the run and setup screens.

a. **Clearing Total Volume Infused.** Perform the following to clear the total Volume Infused from the setup screen:

(1) Press the VI soft key.

(2) Observe that displays the message “Press VI again to clear display.”

(3) Press the VI soft key again to clear the total volume infused.

4.2.6 Pump Shut Down. When the pump is powered down it will retain the infusion parameters (including volume infused) and operational setups for a period of one (1) hour. Perform the following to shut down the pump:

a. If an infusion is in process press the START/STOP Channel control key to place the infusion on hold then press the **Cancel A or Cancel B** soft key.

b. Press and hold the control key for two (2) seconds, an audible tone will sound then the pump will power down.

4.2.7 Restoring an Infusion following Pump Power Down. Perform the following to restore an infusion after shutting down the pump:

a. Press the control key.

b. Observe that “Resume Therapy” appears after the self check, if it has been less than one (1) hour since shut down. The display will prompt for the selection of either “New Patient” or “Same Patient.” Press the soft key to select the appropriate choice. (If power has been off for more than one (1) hour, the primary setup screen will display ”New Patient Only”).

c. Press the Rate soft key.

d. Observe that the rate value is highlighted.

e. Adjust the Rate using the numeric keys (or the up and down arrow keys) if necessary.

f. Press Enter to accept value.

g. Observe that the VTBI value is highlighted.

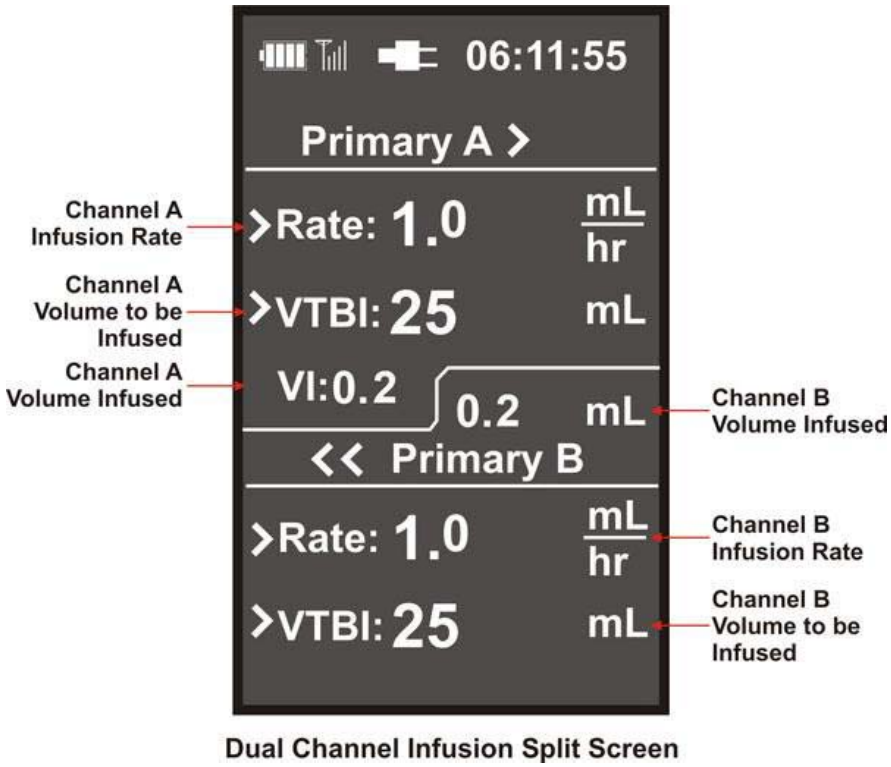
h. Use the numeric keys (or the up and down arrow keys) to change the VTBI value if necessary.

i. Press the VI soft key twice to clear the volume infused if necessary.

4.3 Dual Channel Infusion. The MRidium™ 3860 pump may be configured to perform simultaneous infusions on both Channel A and B (if equipped with the optional SideCar).

4.3.1 Dual Channel Infusion Setup. To perform a dual channel infusion, configure both Channel A and Channel B as described in Paragraph **4.2.** Push the Start/Stop buttons of both channels to begin the infusion. Once both infusions are started, the display screen "splits" to display information for both infusion channels (**Figure 4-2**). During dual channel infusions, any SpO2 related data is shown in the informational display area on the pump, or remote unit's, display(s).

4.3.2 Single Channel/Dual Display Setup. If a single infusion pump channel is operating (either Channel A or Channel B), the large view SpO2 data will be seen in the lower portion of the pumps display (where normally Channel B information is seen (refer to **Figure 7-1**). If Channel B is configured, and the infusion is started, the pump will automatically revert to dual channel display until one of the operating channel's infusion has been stopped or canceled.



Dual Channel Infusion Split Screen

Figure 4-2. Dual Infusion Display

4.4 Secondary Infusion Configuration.

NOTE: The Secondary infusion feature is not available when starting an infusion with the dose rate calculator when using the Dose Error Reduction System (DERS) or with Pump software version 3.0.XXXX or higher.

The MRidium™ 3860 pump supports secondary infusions in the form of automatic sequential piggybacking. Medications must be compatible to be infused in this manner, as they will mix in the tubing below the injection site. When the device is programmed and delivering in the secondary mode, only fluid from the secondary container is being delivered to the patient as the primary infusion is temporarily stopped. Delivery from the primary container resumes when the fluid level in the secondary line equilibrates with, or is even with, the fluid level in the primary container.

There are key elements in setting up and delivering a secondary infusion.

- Head height differential. To prevent sympathetic flow (flow from the primary container), the secondary container must be at least 9.5 inches (24 cm) higher than the primary container.
- The clamp on the secondary set must be opened. If the clamp is not opened, the fluid will be delivered from the primary container.

WARNING: The secondary VTBI settings require consideration of such variables as factory overfill, medication additions, etc. Underestimating the volume will cause the remaining Secondary solution to be infused at the Primary rate; overestimating will result in the Primary solution being infused at the secondary rate. Multiple doses from a single container are not possible.

WARNING: The Secondary set must be primed prior to beginning the Secondary infusion.

4.4.1 Priming a Secondary Administration Set. Any secondary set can be used with the MRidium™ 1000 Series I.V. Set. The secondary set must be primed prior to beginning the secondary infusion. The secondary set may be primed in one of two ways: 1.) Forward Priming: Gravity prime using the secondary fluid, or 2.) Back Priming: Priming the secondary line using the fluid from the primary container (the back priming technique minimizes the amount of wasted medication that might occur using the Forward Priming technique).

NOTE: The Back Priming technique may be used for subsequent doses of medication.

If there is any question on drug incompatibilities, consult with the hospital pharmacist before performing the Back Prime technique.

a. **Back Priming Technique.** Perform the following to back prime a secondary administration set (using aseptic technique):
   (1) Spike secondary medication bag and clamp secondary tubing.
   (2) Attach the secondary set to the upper injection port on the primary administration set.
   (3) Lower the secondary fluid container below the upper injection port on the primary administration set.
   (4) Open the clamp on the secondary set to allow fluid from the primary to “back prime” into the secondary line
   (5) When the secondary set is completely primed, close the clamp and suspend the secondary container on the I.V. pole higher than the primary fluid container.

4.4.2 Secondary Infusion Setup Perform the following to setup a secondary infusion:

a. Lower the primary fluid container onto a non-magnetic hanger (may be enclosed with the secondary administration set). Verify hanger is non-magnetic prior to use. This will allow the pump to pull from the secondary fluid container.
b. Attach the primed secondary set to the upper injection port of the primary administration set or back prime as above.
c. Open the clamps on both the primary and secondary administration sets.
d. When the fluid level in the secondary line equilibrates with the fluid level in the primary container, flow from the primary fluid container resumes.

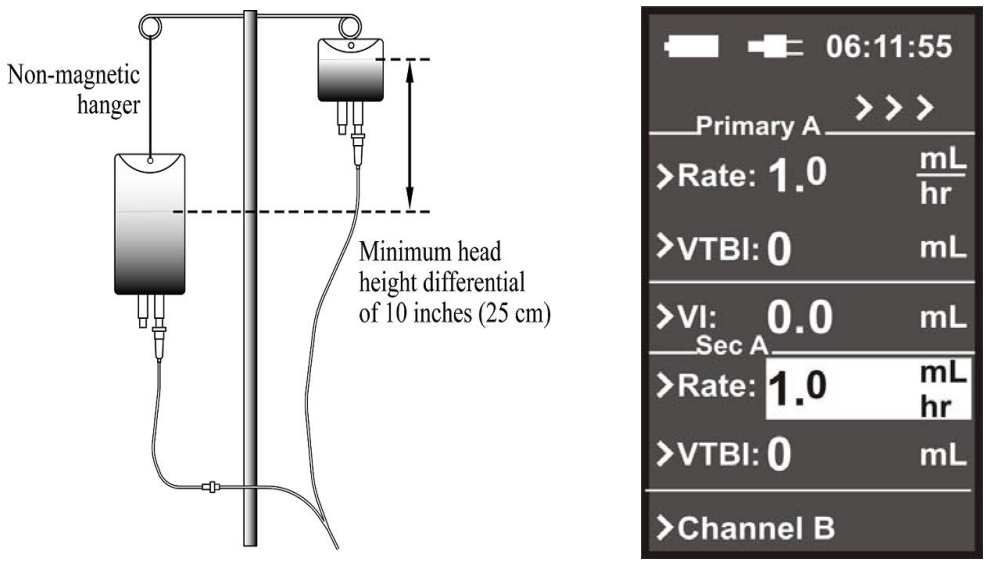


Figure 4-3. Secondary Infusion Set-up and Programming Screen

4.4.3 Programming a Secondary Infusion. Perform the following to program a secondary infusion:

a. Press the SECONDARY soft key.

b. Observe that the programming screen splits to display Secondary Rate and VTBI with the Rate value highlighted (**See Figure 4-3**).

c. Enter the desired flow rate using the numeric keys (or the up and down arrow keys).

d. Press Enter or VTBI soft key.

e. Observe that the VTBI value is highlighted.

f. Enter the desired volume to be infused using the numeric keys (or the up and down arrow keys).

g. Observe that the Ready to Start prompt is displayed.

h. Press the START/STOP Channel control key.

i. Observe that the secondary Rate and VTBI is displayed on the main display screen.

- The green infusion running indicator light flashes.
- Confirm flow from the secondary fluid container by observing the drip chamber.

- When the VTBI = 0 mL, the pump gives an audible alarm and the primary parameters resume and are displayed.

WARNING: The clamp on the secondary set must be opened. If the clamp is not opened, the fluid will be delivered from the primary container.

The Secondary VTBI must be equal to the volume in the secondary container. Variables such as factory overfill and the amount of medication must be considered when programming the VTBI.

Underestimating the secondary VTBI will result in the remainder of the secondary solution to be delivered at the primary rate.

4.4.4 Viewing Primary Settings during a Secondary Infusion. It is possible to view the primary settings while a secondary infusion is in process. Perform the following to view the primary settings during a secondary infusion:

a. Press the Adjust Primary soft key.

b. Observe that the primary parameters are now displayed on the central display screen with the secondary infusion continuing without interruption.

c. Press the CANCEL soft key to return to the secondary run screen (or wait fifteen (15) seconds for Timeout Return).

4.4.5 Changing Primary Settings during a Secondary Infusion. It is possible to change the primary settings while a secondary infusion is in process. Perform the following to change the primary settings during a secondary infusion:

a. Press the Adjust Primary soft key.

b. Observe that the Primary parameters are displayed with the Rate value highlighted.

c. Press the RATE or VTBI soft key and set the new parameter(s) using the numeric keys (or the up and down arrow keys).

d. Press Enter to accept the new values and return to Secondary display, or press the CANCEL soft key to return to the secondary run screen.

4.4.6 Stopping a Secondary Infusion and Returning to Primary Infusion. Perform the following to stop a secondary infusion and return to the primary infusion:

a. Press the START/STOP Channel control key.

b. Observe that **Cancel (A) or (B)** is displayed as a soft key option.

c. Press Cancel (A) or (B) soft key.

- The pump is on hold and the light is not on.

d. The Primary infusion programming screen will display.

- To stop flow from the secondary container, the clamp on the secondary set must be closed or the set disconnected from the upper injection port.

e. Press START/STOP to restart at primary settings.

4.4.7 Dual Channel Operation. When both channel A and B are running, the options for viewing and changing the primary settings when a secondary infusion is running move to the “Menu”. To view or change the primary settings:

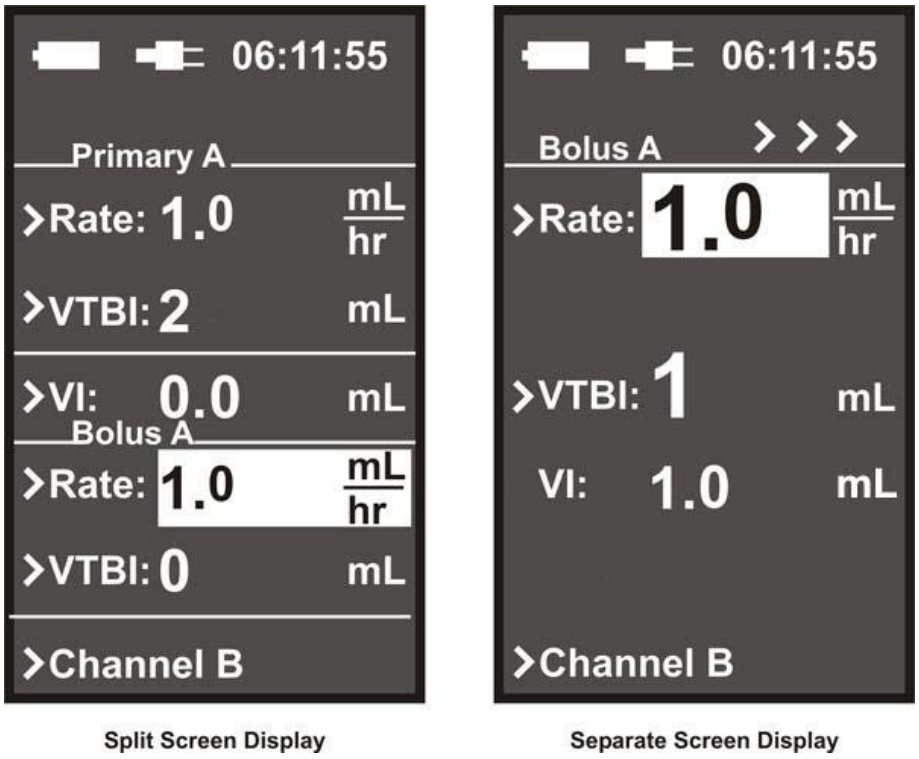
a. Select MENU Key.

b. Press Primary A or Primary B Soft Key

c. Verify that Primary A Rate is highlighted. Use UP or DOWN arrow keys to change if necessary.

d. Press VTBI Soft Key. Use UP or DOWN arrow keys to change if necessary. Press ENTER to save changes and return o run screen.

e. Press CANCEL to return to split running screen without making changes.



Split Screen Display Separate Screen Display

Figure 4-4. Bolus Setup Displays

4.5 Bolus Delivery. The Bolus feature is used to deliver a bolus. The operator enters this feature by selecting the Bolus option in the menu on the setup screen or the running screen.

4.5.1 Bolus Setup and Start. The Bolus option may be programmed at the start of an infusion or added to an infusion in progress. Perform the following to program a Bolus Dose for infusion:

NOTE: The VTBI of the Bolus cannot exceed the VTBI of the Primary infusion.

a. **Bolus A Soft Key:** If the Channel B SideCar Option is installed and Channel A channel is running pressing this soft key will allow Bolus A selection.

b. **Bolus B Soft Key:** If the Channel B SideCar Option is installed and Channel B channel is running pressing this soft key will allow Bolus B selection.

c. Press BOLUS soft key from either the Primary programming, running screen or menu.

- If from the primary programming screen the screen will split for Bolus information (**See Figure 4-4**).
- If from the primary running screen, a separate Bolus display will appear (**See Figure 4-4**).
- When both channels are running, the Bolus option is accessed from the “Menu.” The screen will display “Bolus” for the channel chosen.

d. Observe that the Rate is highlighted.

e. Use the numeric keys (or up and down arrow keys) to enter the Bolus delivery (the rate defaults to 500 mL/Hr, or other units as selected in the Dose Rate Calculator).

f. Press the VTBI soft key.

g. Use numeric keys (or the up and down arrow keys) to enter Bolus VTBI value.

h. Press Enter to accept (this starts the Bolus if programmed while the pump is running).

i. If pump was not running, press the START/STOP Channel control key to begin Bolus infusion.

j. Upon completion of the Bolus infusion, an audible alert sounds and the primary infusion rate resumes with the VTBI counting down.

4.5.2 Stopping Bolus Rate Dose. Perform the following to stop a Bolus Dose infusion:

a. Press START/STOP Channel control key

b. Press Cancel (A) or (B) soft key.

c. Observe that the **Push Start (A) or (B)** prompt is displayed.

d. Press the START/STOP Channel control key to resume the Primary infusion parameters.

4.5.3 Restoring Bolus Dose. A Bolus Dose can be restored after it is complete. Perform the following to restore a Bolus Dose:

a. Press BOLUS soft key from running screen or Menu.

b. Verify dosing parameters and press Enter control key. The Bolus begins immediately.

NOTE: Confirm the primary mode parameters are correct before accessing the Bolus Dose option. Bolus VTBI must be less than the primary VTBI.

Figure 4-5. Attaching Channel B "SideCar"

4.6 Channel B. (3861 I.V. Pump SideCar™) A second channel may be added to the MRidium™ pump. Perform substep **4.6.1** to add the Channel B SideCar and substep **4.6.2** to remove the Channel B SideCar.

IMPORTANT: 3861 Sidecar™ can only be used with 3860 or 3860+ Pumps. Earlier model 3851 Sidecar™ pumps will not operate with these units.

4.6.1 Attaching the Channel B SideCar. Perform the following to attach the Channel B SideCar:

a. Turn 3860 Pump OFF.

b. Remove SideCar port protector cap on rear of 3860 Pump. (Do not discard protector cap).

c. Position the Channel B SideCar **(See Figure 4-5)** next to the left side of MRidium™ 3860 Pump

d. Slide the Channel B SideCar connection port onto the pump, press together and tighten two (2) thumb screws on the rear. Tighten upper and lower screws a little at a time until secure. Do not overtighten the thumbscrews.

e. Turn ON pump and verify start-up checkout (refer to section **4.2**).

4.6.2 Detaching the Channel B SideCar. Perform the following to detach the Channel B SideCar:

a. Turn 3860 Pump OFF.

b. Slide the Channel B SideCar backward to disconnect from main pump after loosening upper and lower thumb screws.

c. Re-attach SideCar port protector cap on rear of 3860 pump.

4.7 Special Features Menu. There are additional features that are accessed by pressing the MENU control key. Pressing the MENU control key brings up the Special Feature Setup Menu to provide the operator with the ability to set the Dose Rate Calculation, adjust the Alarm Volume, set the KVO Rate and adjust the Occlusion Limit. Depending on optional accessories (i.e. Remote or Channel B) user may also lock keyboard, set communication channel for Remote Display, program Bolus or change/view primary infusion from this screen.

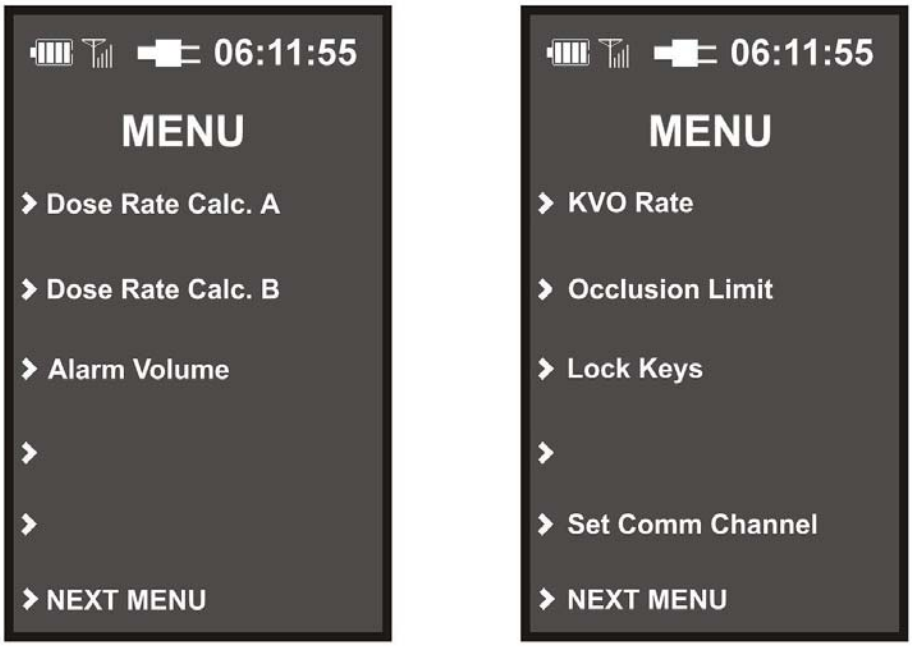


Figure 4-6. Special Feature Setup Menu

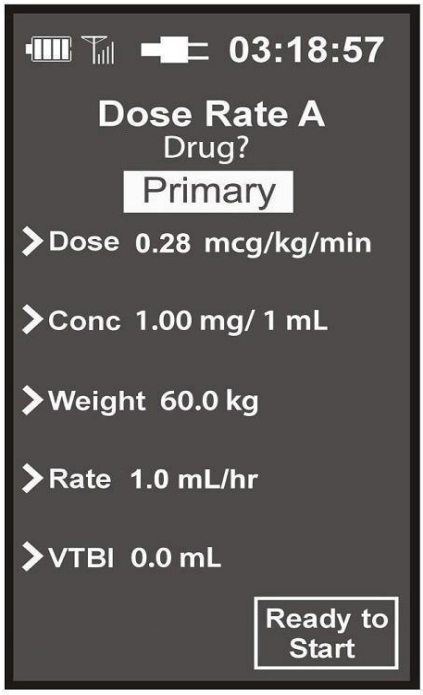


Figure 4-7. Dose Rate Calculation Menu

4.7.1 Dose Rate Calculation. The MRidium™ 3860 infusion pump automatically calculates a Rate based on a Dose amount, Patient Weight, and Concentration of medication. There are three (3) modes of operation: the Basic Dose Rate Calculator, the Dose Rate Calculator with Drug Library, and the Dose Rate Calculator with User-Defined Drug Library.(Refer to chart below and Default Values Table in Appendix A).

Dose Rate Calculator w/Drug Library

Dose Rate Calculator can be used for Primary, Secondary or Bolus infusions.

A. Drug Library

1. Drug? (Default)
2. Propofol
3. Dobutamine
4. Adenosine
5. Dexmedetomidine

Dose Rate Calculator Default Values Table provided in Appendix A.

WARNING: Selection of any drug from the Dose Rate Calculator Library will replace all user set values to the default values described in the Default Values Table in Appendix A. Verify all selections prior to beginning the infusion.

B. Dosing Units

1. Original Dose Units:

mg/kg/min mg/kg/hr mcg/kg/min mcg/kg/hr

2. Volume over Time Dose Units:

mcg/kg	0.00 - 9999
mg/kg	0.00 - 9999
Time Field	1 - 99 min

3. Non Weight Based Dose Units:

mg/hr mg/min
mcg/hr mcg/min
No Weight Entry

Messages are developed to indicate if calculated values exceed the Rate or VTBI specifications: **Und** (under-range) or **Ovr** (over-range) denote settings outside the established limits:

Rate: 0.1 to 99.9, 100 to 1400 mL/hr
VTBI: 0.1 to 999 mL

NOTE: Drug Library can be enabled/disabled from the Service Mode. This feature should only be set by qualified service personnel, as described in the 1125 Service manual.

NOTE: Selecting a different drug name in the Drug Library changes the previous concentration and dose rate values to the default values appropriate for the selected drug. The choice of drug names cannot be modified by the user.

4.7.1.1 Basic Dose Rate Calculator - The Dose Rate Calculator feature is used to calculate the volumetric rate for either Channel A or B, and is accessed using the Menu key. The user is free to change the value of any field at any time. When a new infusion rate is entered the dose value will change. When a new dose value, weight, concentration or diluent value is entered the infusion rate changes automatically. In this mode, the Drug Library is turned off in the Service Mode.

NOTE: Secondary user preset values use the primary infusion preset values for the medication selected. Separate secondary preset values can not be saved.

The example shown in **Figure 4-7** is for Channel A. However, the dose calculation screen used for channel B is the same except for the title and the soft key text that is used to go to Channel A's dose calculation screen. Once the dose calculation screen has been successfully completed, the dose rate a "Ready to Start" message will appear in the lower, right-hand corner of the display. This message is used to indicate that the user may press the "Start/Stop Channel" control key for the appropriate channel.

Perform the following steps to select the Dose Rate Calculator:

a. Press the MENU control key.

b. Press the DOSE RATE CALC. (A or B) soft key. "Dose Rate Calc. B" message will only be visible if the Sidecar™ (Channel B) has been connected.

c. Observe that the Dose Rate Calculation Menu (**See Figure 4-7**) will be displayed with the word "Primary" highlighted.

d. Use the up and down arrow keys to select Primary, Secondary or Bolus.

e. Press Enter.

f. Observe that the word "**Drug?**" is highlighted, which is the default drug name.

NOTE: All factory default values in the Drug? Screen are shown in Appendix A, and the user must enter appropriate values for all parameters before an infusion can begin.

NOTE: In software revision 3.2.9 and higher, the Dose Rate Calculator Bolus feature now defaults the Bolus Dose Units to "mL" so that the initial Bolus setting choices are Volume and Time for any Bolus infusion, rather than the Rate & Volume setting choices. With these new default settings, the Time default value is set to 1 minute. All other Bolus Dose Units are still available (e.g. mcg/kg/hr, mcg/kg, etc.), if appropriate, for the Dose Rate Calculator during programming.

g. Press ENTER or the DOSE soft key.

h. Observe that the Dose value is highlighted. Use the numeric keys (or the up and down arrow keys) to set the desired Dose value. Press ENTER, or the DOSE soft key. Observe that the units are highlighted. Use the up and down arrow keys to choose the correct unit ordered.

NOTE: All available units choices for the dose and concentration settings are provided in Table 3 in Appendix A.

i. Press ENTER or the CONC (concentration) soft key.

j. Observe that the concentration value is highlighted. Use the numeric keys (or the up and down arrow keys) to enter the concentration of the medication to be infused. Press ENTER, or the CONC soft key to highlight the concentration units. Use the up and down arrow keys to set the concentration units (see Table 3 in Appendix A for available choices).

NOTE: Additional units choices for the dose and concentration settings are available in software revision 3.0.XXXX and higher. Refer to Table 3 in Appendix A for the list of these choices.

k. Press ENTER or the CONC soft key to highlight the base of the concentration if it is greater than 1 mL. Use the numeric keys (or the up and down arrow keys) to select this value.

l. Press ENTER or the WEIGHT soft key.

m. Observe that the Weight value is highlighted.

NOTE: If the patient weight is in pounds, divide that value by 2.2 to get weight in kilograms.

n. Use the numeric keys (or the up and down arrow keys) to enter the patient's weight in kg.

o. Press the appropriate VTBI, or Time (if displayed) soft key.

p. Observe that the selected value is highlighted.

q. Use the numeric keys (or the up and down arrow keys) to select the value. Press ENTER to complete the selection.

r. The rate will automatically be calculated and the **Ready to Start (A) or (B)** prompt will appear.

s. Verify all entered values before starting infusion.

t. Press the START/STOP Channel control key. The Main running screen will display with the correct parameters from the Dose Rate calculation screen with the Dose value displayed between the Rate and VTBI parameters (**See Figure 4-8**).

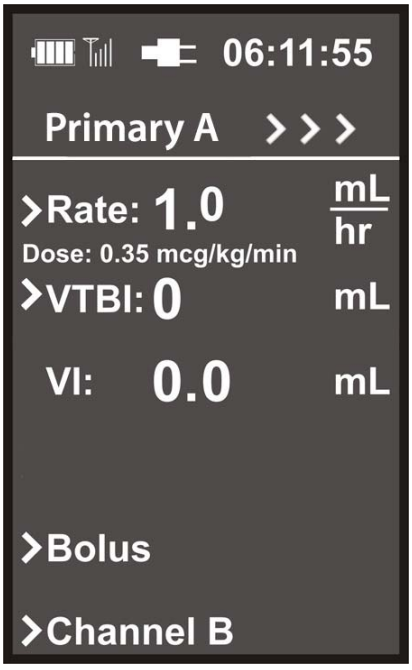


Figure 4-8. Primary Screen with Dose Rate Displayed

4.7.1.2 Dose Rate Calculator with Drug Library - The Dose Rate Calculator feature is used to calculate the volumetric rate for either Channel A or B, and is accessed using the Menu key. All factory default values in the Drug Library are shown in Appendix A, and the user must enter appropriate values for all parameters before an infusion can begin. The user is free to change the value of any field at any time. When a new infusion rate is entered the dose value will change. When a new dose value, weight, concentration or diluent value is entered the infusion rate changes automatically. In this mode, the Drug Library is turned on in the Service Mode, but no user-defined parameters have been programmed.

Perform the following steps to select the Dose Rate Calculator with Drug Library Calculator:

a. Press the MENU control key.

b. Press the DOSE RATE CALC. (A or B) soft key. "Dose Rate Calc. B" message will only be visible if the Sidecar™ (Channel B) has been connected.

c. Observe that the word "Drug?" is highlighted.

d. Use the up and down arrow keys to select the drug type (the choices are: Drug? (which is the default drug name), Adenosine, Dobutamine, Propofol, or Dexmedetomidine).

e. Press Enter.

f. Observe that the Dose Rate Calculation Menu (See Figure 4-7) will be displayed with the word "Primary" highlighted.

g. Use the up and down arrow keys to select Primary, Secondary or Bolus.

h. Press ENTER or the DOSE soft key.

i. Observe that the Dose value is highlighted. Use the numeric keys (or the up and down arrow keys) to set the desired Dose value. Press ENTER, or the DOSE soft key. Observe that the units are highlighted. Use the up and down arrow keys to choose the correct unit ordered.

NOTE: All available units choices for the dose and concentration settings are provided in Table 3 in Appendix A for the list of these choices.

NOTE: In software revision 3.2.9 and higher, the Dose Rate Calculator Bolus feature now defaults the Bolus Dose Units to “mL” so that the initial Bolus setting choices are Volume and Time for any Bolus infusion, rather than the Rate & Volume setting choices. With these new default settings, the Time default value is set to 1 minute. All other Bolus Dose Units are still available (e.g. mcg/kg/hr, mcg/kg, etc.), if appropriate, for the Dose Rate Calculator during programming.

j. Press ENTER or the CONC (concentration) soft key.

k. Observe that the concentration value is highlighted. Use the numeric keys (or the up and down arrow keys) to enter the concentration of the medication to be infused. Press ENTER, or the CONC soft key to highlight the concentration units. Use the up and down arrow keys to set the concentration units (see Table 3 in Appendix A for available choices).

NOTE: Always program concentration first for fastest drug entries.

l. Press ENTER or the CONC soft key to highlight the base of the concentration if it is greater than 1 mL. Use the numeric keys (or the up and down arrow keys) to select this value.

m. Press ENTER or the WEIGHT soft key.

n. Observe that the Weight value is highlighted.

NOTE: If the patient weight is in pounds, divide that value by 2.2 to get weight in kilograms.

o. Use the numeric keys (or the up and down arrow keys) to enter the patient's weight in kg.

p. Press the appropriate Rate, VTBI, or Time (if displayed) soft key.

q. Observe that the selected value is highlighted.

r. Use the numeric keys (or the up and down arrow keys) to select the value. Press ENTER to complete the selection.

s. The rate will automatically be calculated and the Ready to Start (A) or (B) prompt will appear.

t. Verify all entered values before starting infusion.

u. Press the START/STOP Channel control key. The Main running screen will display with the correct parameters from the Dose Rate calculation screen with the Dose value displayed between the Rate and VTBI parameters (**See Figure 4-8**)

4.7.1.3 User Defined Drug Library settings (Internal Drug Library)- The Dose Rate Calculator feature is used to calculate the volumetric rate for either Channel A or Channel B and is accessed using the Menu key. All starting user-defined values in the Drug Library are preset by service personnel, or the user can enter alternate values for any parameter to begin an infusion. The user is free to change the value of any field at any time. When a new infusion rate is entered the dose value will change. When a new dose value, weight, concentration or diluent value is entered the infusion rate changes automatically. In this mode, the Drug Library is turned on in the Service Mode, and the user-defined parameters have been programmed.

NOTE: In this operating mode, the User-Defined Drug Library settings must be set in the Service Mode. If no values have been set in the Service Mode, the factory default values shown in Appendix A will be seen. The choice of drug names cannot be modified by the user.

IMPORTANT: If the patient weight is entered and started on Channel A, if Channel B is selected, the same weight will be entered on Channel B. However, the patient weight can be changed without affecting the Channel A weight. These two separate weights are retained on their respective channel until “NEW PATIENT” is selected.

Perform the following steps to select the Dose Rate Calculator with User-Defined Drug Library Calculator:

a. Press the MENU control key.

b. Press the DOSE RATE CALC. (A or B) soft key. "Dose Rate Calc. B" message will only be visible if the Sidecar™ (Channel B) has been connected.

c. Observe that the medication name is highlighted. In this mode, the first programmed medication in the service mode will appear first.

NOTE: If user-preset values for “Drug?” have been programmed in the service mode, this label is changed to “Custom” to differentiate it from the default drug name on the pump. “Drug?” may still be visible on the Remote/Charger unit.

d. Use the up and down arrow keys to select the drug type (the choices are: Custom or Drug? (which is the default drug name), Adenosine, Dobutamine, Propofol, or Dexmedetomidine).

e. Press Enter.

f. Observe that the Dose Rate Calculation Menu (See **Figure 4-7**) will be displayed with the word "Primary" highlighted.

g. Use the up and down arrow keys to select Primary, Secondary or Bolus.

NOTE: Selecting a different drug name in the Drug Library changes the previous concentration and dose rate values to the user-defined values for the selected drug. If no User-Defined values are programmed, the parameters in the Drug Library are preset with factory default values, and the user must enter appropriate values for all parameters before an infusion can begin.

NOTE: In software revision 3.2.9 and higher, the Dose Rate Calculator Bolus feature now defaults the Bolus Dose Units to “mL” so that the initial Bolus setting choices are Volume and Time for any Bolus infusion, rather than the Rate & Volume setting choices. With these new default settings, the Time default value is set to 1 minute. All other Bolus Dose Units are still available (e.g. mcg/kg/hr, mcg/kg, etc.), if appropriate, for the Dose Rate Calculator during programming.

h. Press ENTER or the DOSE soft key.

i. Observe that the Dose value is highlighted. Use the numeric keys (or the up and down arrow keys) to set the desired Dose value. Press ENTER, or the DOSE soft key. Note that the units can not be modified from the user preset values in this mode.

j. Press ENTER or the CONC (concentration) soft key.

k. Observe that the concentration value is highlighted. Use the numeric keys (or the up and down arrow keys) to enter the concentration of the medication to be infused. Press ENTER, or the CONC soft key to highlight the concentration units. Note that the units can not be modified from the user preset values in this mode.

l. Press ENTER or the CONC soft key to highlight the base of the concentration if it is greater than 1 mL. Note that the units can not be modified from the user preset values in this mode.

m. Press ENTER or the WEIGHT soft key.

n. Observe that the Weight value is highlighted.

NOTE: If the patient weight is in pounds, divide that value by 2.2 to get weight in kilograms.

o. Use the numeric keys (or the up and down arrow keys) to enter the patient's weight in kg.

p. Press the appropriate Rate, VTBI, or Time (if displayed) soft key.

q. Observe that the selected value is highlighted.

r. Use the numeric keys (or the up and down arrow keys) to select the value. Press ENTER to complete the selection.

s. The rate will automatically be calculated and the Ready to Start (A) or (B) prompt will appear.

t. Verify all entered values before starting infusion.

u. Press the START/STOP Channel control key. The Main running screen will display with the correct parameters from the Dose Rate calculation screen with the Dose value displayed between the Rate and VTBI parameters (**See Figure 4-8**)

v. When infusing, the rate and dose are automatically transferred to the main programming screen for viewing during this and subsequent infusions.

IMPORTANT: The dose variables (dose and time) displayed on the running screen can vary by very small amounts if the infusion is stopped and re-started without re-starting from the Dose Rate Calculator. When infusing, the original parameter programmed in the Dose Rate Calculator are used. Always verify the Dose Rate Calculator parameters for any subsequent or repeat infusion with the same patient.

IMPORTANT: If the patient weight is entered and started on Channel A, if Channel B is selected, the same weight will be entered on Channel B. However, the patient weight can be changed without affecting the Channel A weight. These two separate weights are retained on their respective channel until “NEW PATIENT” is selected.

4.7.1.4 Dose Rate Calculator with Dose Error Reduction System (DERS)

Refer to Section 8 for operation of the Dose Rate Calculator with user defined drug library and the optional Dose Error Reduction System (DERS).

Figure 4-9. Alarm Volume Adjustment Screen

4.7.2 Alarm Volume The MRidium™ 3860 MRI Infusion Pump allows the clinician to adjust the audio volume for user alerts and alarms (**See Figure 4-9**). The pump will sound the alarm during adjustment to provide an indication of the current setting of the volume. The volume range is on a visual sliding scale. Perform the following to adjust the Alarm Volume:

a. Press the MENU control key.
b. Press the ALARM VOLUME soft key.
c. Press the up and down arrow control keys to adjust the volume.
d. Press ENTER.
e. Press the CANCEL control key to return to the run or programming display screen

NOTE: The Alarm Volume setting in the MENU option of the Pump and Remote Display/Charger only controls the unit being adjusted. Adjusting the Alarm Volume setting on the Remote Display will not change the Alarm Volume setting of the Pump.

NOTE: Setting the alarm volume also sets the SpO_2 Pulse Tone volume when it is installed and enabled (3860+ only).

4.7.3 KVO Rate. The MRidium™ 3860 MRI Infusion Pump will default to a preset KVO (Keep Vein Open) rate when the Primary infusion VTBI counts down to 0 mL. When the VTBI is 0 mL, the infusion automatically switches to the configured KVO rate, or remains at the programmed primary flow rate, whichever is less. This KVO rate may be set to a value between 0-5 mL/hr, according to your hospitals policy, from the Special Feature Setup Menu. Perform the following to adjust the KVO Rate:

NOTE: When the KVO rate is set to 0 (off), and the infusion is complete, the short tone will occur, and the infusion will stop. As with a paused infusion, the pump will give a periodic audible tone every 15 seconds to remind the operator that the pump is not infusing (unless the reminder beep has been set to “OFF” in the service mode). When the infusion is paused, “STBY” symbol is displayed adjacent to the paused channel. To continue, press the “CANCEL” key to access the set-up screen.

a. Press the MENU control key.
b. Press the KVO Rate soft key.
c. Press the soft key corresponding to the Channel you wish to change (if the optional second channel is not present then only Channel A will be available).

NOTE: Always select the appropriate KVO rate for the prescribed fluid therapy.

d. Use the up and down arrow control keys to adjust limit between 0-5 mL/hr. (0 shuts off the KVO infusion).
e. Press ENTER.
f. Press the CANCEL control key to return to the main programming screen.

NOTE: This option may appear on the second Menu page.

4.7.4 Occlusion Limits. The MRidium™ 3860 MRI Infusion Pump will display an Inlet Occlusion alarm when there is an occlusion between the infusion fluid source and the pump. Patient Occlusion alarm will display when there is an occlusion between the pump and the patient; this alarm has an adjustable pressure limit between 1-10 PSI (6.9 to 68.8 kPa). Occlusion is detected by building of pressure in the I.V. Line downstream of the pump.

NOTE: If the alarm recurs without apparent cause, the Occlusion Pressure Limit may be set too low. Readjust Occlusion Pressure Limit accordingly. Ensure that occlusion pressures chosen are clinically appropriate.

Perform the following to adjust the Occlusion Pressure Limit:

a. Press the MENU control key.

b. Press the OCCLUSION LIMIT soft key.

c. Use the up and down arrow control keys to adjust limit between 1-10 PSI (6.9 to 68.8 kPa).

d. Press ENTER.

e. Press the CANCEL control key to return to the main programming screen.

NOTE: Dual Channel Operation: The KVO Rate and the Occlusion Limit apply to both Channel A and Channel B.

4.7.5 Lock Keys. This feature allows the user to prevent an accidental key activation. The Lock Key option will not be displayed unless it has been enabled in the Service Mode.

Perform the following to activate Key Lock:

a. Press the MENU control key.

b. Press the LOCK KEYS soft key.

c. Verify all keys are locked except Menu.

d. If any other key is pressed a tone will occur to denote that key is locked.

Perform the following to deactivate Key Lock:

a. Press the MENU control key.

b. Press the UNLOCK KEYS soft key.

c. Verify all keys are now unlocked.

This feature is reserved for service personnel to enable, contact Service/Biomedical department for activation (details of this activation are included in the MRidium™ 3860 MRI Infusion Pump Service Manual, part number 1125). This option may appear on the second Menu page.

4.7.6 NEXT MENU key The NEXT MENU will appear if the Remote Display option or the Channel B SideCar option is installed, pressing the NEXT MENU soft key will display additional menu options.

a. **Set Comm Channel:** If the remote control option is installed pressing this soft key will select the Radio Channel selection menu.

WARNING: Upon signal reacquisition between the Pump and the Remote Display, always visually confirm that both Pump and Remote displays change with a selection of the MENU key (this won't affect the Pump operation if it is infusing).

If using multiple Pumps with the same Remote Display/Charger, always program each Pump with its unique radio-link channel (Channels 1 through 6) in the Setup Menu. Additionally, when changing the Remote Display/Charger radio-communication channel, always re-confirm proper communication with the selected Pump. This can be done in many ways, but the easiest way is to select the MENU key on the Remote Display/Charger and visually confirm that the Pump's display matches this change. Pressing the CANCEL key on the Remote Display/ Charger should then return both displays to the original display. Doing this at least once before any Pump programming will acknowledge that proper communication has been established between the Remote Display/Charger and the selected Pump.

4.7.7 Radio Channel menu. Press the Channel soft key to highlight the desired channel. Both Remote and Pump must be set to the same channel.

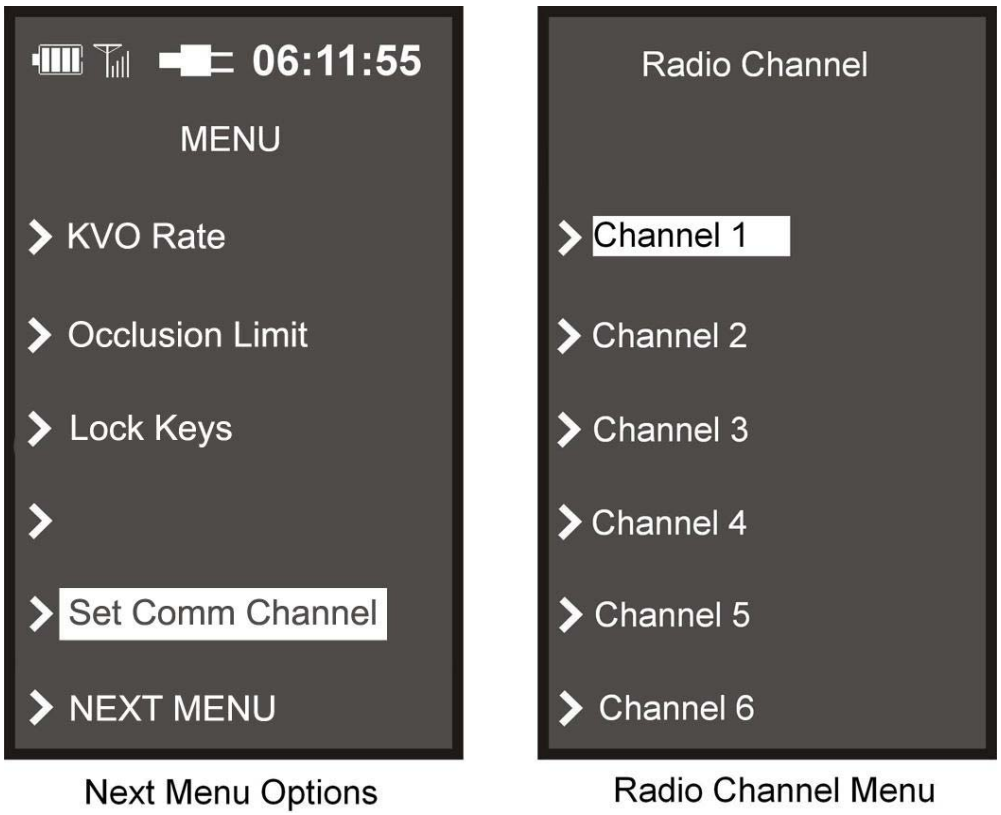


Figure 4-10. Set Comm Channel Displays

4.7.8 Exiting the Special Features Menu. To exit the Special Features Menu, press the **MENU or CANCEL** control key. The pump will return to the Primary Pump Setup screen where setup of the Primary Pump may be performed.

4.8 Air Bubble Detection and Reset. The pump has an air bubble detector that will detect air bubbles (that are greater than 100 uL) which pass in front of it. When this happens the infusion will stop and the pump will alarm. Once the condition has been corrected the infusion cycle must be manually restarted.

4.9 Data Retention. The pump program settings and option selections are retained in nonvolatile memory. If the pump has been turned off for longer than one (1) hour, delivery settings are cleared. The History Log data, which stores a comprehensive range of the pumps operational information, is retained indefinitely on a FIFO (First In - First Out) basis. The History Log holds approximately 3,000 to 5000 entries and alarms. It can be downloaded from the Pump into a computer to review. This is accessed in the Service mode. (Please see Service Manual 1125 for more details).

SECTION 5
ALARMS

5.0 Alarms.

5.1 Introduction.

5.2 User Messages. There are three (3) types of user messages (Alarms, Alerts and User Prompts) displayed on the pump. The following is a description of the user messages:

a. **Alarm.** Major Pump or Channel related problem.

- The infusion stops.
- The RUN/ALARM Lamp illuminates RED and flashes
- The audible alarm tone sounds
- An alarm message can appear at top of Main Display

b. **Alert.** Indicates a change in the infusion status.

- The infusion continues to operate
- The RUN/ALARM Lamp illuminates GREEN and flashes
- The audible tone sounds
- An alert message can appear at top of Main Display

NOTE: During SpO2 related Alerts/Alarms, the infusion does not stop, and the Run/Alarm lamp can flash both green and red together during these events.

c. **User Prompt.** Informational update, the infusion status has not changed.

- Generally, some steps were not completed or an incorrect key was pressed.
- Prompt message can appear at top of Main Display.

NOTE: When using the Pump with both Channel A and Channel B operating, some messages will indicate “Channel A” or “Channel B” to identify which channel is affected. Always verify the appropriate channel is selected before making any changes. If both channels are alarming, both RUN/ALARM indicators will be flashing RED and the alarm message at the top of the Main Display will alternate both messages.

See **Table 5-1** for a listing of all the messages (Alarms, Alerts and User Prompts) that the pump might display. The table is divided into four columns with the first column providing the message which appears on the screen, the second identifies the type of message (Alarm, Alert or User Prompt), the third identifies the cause of the message and the fourth contains the suggested action in response to the message.

5.3 Responding to an Alarm. Perform the following to respond to an alarm:

a. Press the Alarm Silence

control key to silence the sound and re-set the Alarm Condition monitor.

b. Resolve the alarm condition (i.e.: clear bubble, change battery, close door, etc.)

c. Press the Start/Stop control key for the appropriate channel to continue the infusion.

5.4 Remote Alarms. All alarms must be resolved at the pump. Alarms are listed in **Table 5-1.**

WARNING: Always Respond to patient at the pump if an alarm occurs. Do not rely on the remote alarm silence function. Patient injury could occur.

Table 5-1. Alarm, Alert and User Prompt Messages

MESSAGE	TYPE	CAUSE	RESOLUTION
BAD BATTERY	Alert	Battery fault has occurred	Remove from use. Contact qualified service personnel
BATTERY DEPLETED	Alert	Battery is too low to operate Pump much longer.	Plug AC Adapter power cord into an AC outlet immediately. Make sure Adapter is plugged into the Pump.
Battery Low	Alert	Battery has 30 minutes or less of charge remaining.	Plug Pump into AC Adapter, and/or AC Adapter power cord into an AC outlet as soon as possible.
Bubble Detected (A) or (B)	Alarm	Air detector has detected an air bubble larger than the 100 uL threshold.	Evaluate air in set. Open Pump Door latch to remove set. Remove air per hospital protocol. Reinstall set. Press START/STOP to resume infusion.
Changes not allowed (DERS Only)	Prompt	Titration from the running screen is the only method of dose adjustment, unless the infusion is stopped.	Press CANCEL to switch to the main Running screen to modify the active parameters (e.g. Dose, VTBI, or Time, dependent on the infusion settings). Otherwise, press START/ STOP to stop the infusion, then press CANCEL, then access the Dose Rate Calculator Menu to modify any of the infusion parameters.
Check Door (A) or (B)	Alarm	Possible free flow of I.V. fluid	Be sure door clamp is closed tightly flush with door. Open and reclose door or assure Free Flow Preventer is pulled out to stop position.
Close Door (A) or (B)	Alarm	Latch was opened during an infusion.	Check for proper set installation. Close latch. Press START/STOP to resume infusion.
Close Door (A) or (B)	Prompt	Latch is open (prior to starting an infusion). Message occurs with an audible beep that repeats every 10 seconds.	Close latch fully downward.
Completed	Prompt	Infusion has been completed, and KVO Rate is set to zero (0). Current VTBI = 0. No fluid is infusing at this time.	Press CANCEL to reset infusion to initial parameters. Periodic reminder tone will be heard (unless the reminder beep has been set to “OFF” in the service mode) until user acknowledges the infusion is complete.
Critical Error xxx or Service Code xxx	Alarm	Pump Run Test fails, other motor tests, hardware or software conflict.	Remove from use. Contact qualified service personnel.
DEAD BATTERY	Alarm	Battery too low to operate Pump.	Plug Pump into AC Mains Power. Press ON key and choose “Same Patient” to resume infusion.
Dose Complete (Audible Only)	Alert	A dose delivery has just been completed. Message with an audible beep.	No action necessary. Pump enters KVO.

MESSAGE	TYPE	CAUSE	RESOLUTION
History Checksum Error	Prompt	Pump detected a memory or power failure. Existing operating parameters have been erased.	Pump has reverted to the default program settings. Press MENU to examine settings, and reenter any needed infusion setting changes.
Inlet Occluded (A) or (B)	Alarm	Flow has been obstructed between fluid container and Pump.	Check administration set for probable cause (kinked tubing, clogged filter, etc.). Press Start/Stop (for appropriate channel) to restart infusion.
Load Set (A) or (B)	Prompt	Pump needs to verify operation (establish pressure baseline and perform motor test).	Open Pump Door until message disappears. Close Door to resume infusion. Always turn Pump on prior to loading set.
MAX Rate (Audible Only)	Prompt	Calculated rate is outside allowable range. An audible beep occurs if key is pressed to attempt to move dose out of range.	Verify and reenter settings.
No Communication (Remote Display unit only)	Alert	Communication between pump and Remote Display has been interrupted.	Reposition Remote Display or Pump to re-establish communication. Be sure Pump is still ON. Interference from another Radio source may cause problem. Go to an alternate Comm channel on both Pump and Remote Display. Otherwise, refer unit to qualified service personnel.
OVR	Prompt	Over-Range of Rate or VTBI established settings.	Reset values to be within parameters: Rate: 1.0 to 999 mL/hr VTBI: 0.1 to 9,999 mL
Press ENTER	Prompt	Value change confirmation required.	Verify selection and press ENTER.
Pressure Error (A) or (B)	Prompt	Excessive variation in pressure due to motion, flow from other Pumps or blood pressure prevents accurate setting of pressure baseline.	Open and Close door to reset pressure sensors. Press START/STOP key to start infusion.
Pt Occluded (A) or (B) (Patient Occluded)	Alarm	Pressure in I.V. line has exceeded Adjustable Pressure Limit due to elevated resistance in delivery path between pump and patient.	Check administration set for probable cause (kinked tubing, closed stopcock, high resistance catheter, etc.). Press START/STOP key to restart infusion.
Rate too high	Prompt	Calculated rate exceeds the maximum rate of the pump (i.e. 1400 mL/hr).	Infusion cannot be started with the existing values. Modify the selected parameter to allow the infusion to proceed. Review and verify the new infusion parameter(s) before starting the infusion.

MESSAGE	TYPE	CAUSE	RESOLUTION
Rate too low	Prompt	Calculated rate is below the minimum rate of the pump (i.e. 0.1 mL/hr).	Infusion cannot be started with the existing values. Modify the selected parameter to allow the infusion to proceed. Review and verify the new infusion parameter(s) before starting the infusion.
Recheck Settings, Press Enter to restart	Prompt	Calculated Dose Rate Calculator values are outside allowable range.	Press the ENTER key. Previous values are replaced with default values. Verify and reenter new settings.
Re-enter settings, press ENTER to continue	Prompt	Selected values are outside allowable range.	Press the ENTER key. Previous values are replaced with default values. Verify and reenter new settings.
Review Bolus	Prompt	A selected parameter that affects a Bolus infusion calculated value (e.g. Dose, CONC, Weight, etc.) has been modified after setting up an infusion.	Select the Dose Rate Calculator Bolus Infusion screen. Infusion can't be started without reviewing this setup screen. Review and verify the new infusion parameter(s) before starting the infusion.
Review Primary	Prompt	A selected parameter that affects a Primary infusion calculated value (e.g. Dose, CONC, Weight, etc.) has been modified after setting up an infusion.	Select the Dose Rate Calculator Primary Infusion screen. Infusion can't be started without reviewing this setup screen. Review and verify the new infusion parameter(s) before starting the infusion.
Review Secondary	Prompt	A selected parameter that affects a Secondary infusion calculated value (e.g. Dose, CONC, Weight, etc.) has been modified after setting up an infusion.	Select the Dose Rate Calculator Secondary Infusion screen. Infusion can't be started without reviewing this setup screen. Review and verify the new infusion parameter(s) before starting the infusion.
Settings Lost	Prompt	Message occurs at power up to indicate the existing operating parameters have been erased due to internal battery failure, and the system has reverted back to initial default parameter settings.	Re-enter patient's infusion settings. If message recurs, refer the pump to qualified service personnel for repair.
Unload Set	Prompt	Pump needs to reset air in line detector.	Open door. Remove and replace I.V. set. Close door. Always turn Pump ON prior to loading set.
UND	Prompt	Under-Range of Rate or VTBI established settings.	Reset values to be within parameters: Rate: 1.0 to 999 mL/hr VTBI: 0.1 to 9,999 mL
VTBI = KVO (Audible Only)	Alert	VTBI has counted down to zero. Channel is in KVO mode.	Press the appropriate channel's START/STOP to stop infusion, then press ENTER and the VTBI Soft Key to reenter the new VTBI. Change solution container, if necessary. If therapy is complete, remove tubing from pump to end infusion.

MESSAGE	TYPE	CAUSE	RESOLUTION
VTBI too high	Prompt	Calculated VTBI exceeds the maximum VTBI of the pump (i.e. 999 mL).	Infusion can't be started with the existing values. Modify the selected parameter to allow the infusion to proceed. Review and verify the new infusion parameter(s) before starting the infusion.
VTBI too low	Prompt	Calculated VTBI is below the minimum VTBI of the pump (i.e. 0.1 mL).	Infusion can't be started with the existing values. Modify the selected parameter to allow the infusion to proceed. Review and verify the new infusion parameter(s) before starting the infusion.
X ABOVE HARD limit (DERS only).	Prompt	Selected Channel X (A or B) value exceeds the user-set maximum limit of the parameter stored on the DERS Drug Library Card. The maximum limit is momentarily displayed when this message appears.	Infusion can't be started with the existing values. Modify the selected parameter to within the acceptable limits to allow the infusion to proceed.
X ABOVE soft limit Yes - Enter / Cancel - No (DERS only).	Prompt	Selected Channel X (A or B) value exceeds the user-set High Limit of the parameter stored on the DERS Drug Library Card. The High Limit is momentarily displayed when this message appears.	The user must press ENTER to accept the parameter above the High Limit for the Infusion to begin. Otherwise, the user should press CANCEL (No) to cancel the parameter change. If no entry is made, the change will cancel automatically in 10 seconds.
X BELOW HARD limit (DERS only).	Prompt	Selected Channel X (A or B) value is less than the user-set minimum limit of the parameter stored on the DERS Drug Library Card. The minimum limit is momentarily displayed when this message appears.	Infusion can't be started with the existing values. Modify the selected parameter to within the acceptable limits to allow the infusion to proceed.
X BELOW soft limit Yes - Enter / Cancel - No (DERS only).	Prompt	Selected Channel X (A or B) value is less than the user-set Low Limit of the parameter stored on the DERS Drug Library Card. The Low Limit is momentarily displayed when this message appears.	The user must press ENTER to accept the parameter below the Low Limit for the Infusion to begin. Otherwise, the user should press CANCEL (No) to cancel the parameter change. If no entry is made, the change will cancel automatically in 10 seconds.

Refer to Section **7.8** for SpO_2 related Alarms, Alerts, and user prompt messages.

SECTION 6
BATTERY OPERATION

6.0 Battery Operation.

6.1 Introduction. The 3860 system includes a smart Battery Pack that self-monitors its performance and status and communicates this information to the Pump. This allows the Pump to monitor the battery parameters in order to maximize the life of the battery, reduce battery-related costs and minimize Pump/Battery down-time.

NOTE: The Battery Pack is sealed such that the batteries can't be replaced. If the Battery Pack fails or becomes unusable, do not attempt to replace the internal batteries. Replace the Battery Pack. Contact Iradimed Corporation for disposal.

6.2 Inserting the Battery Pack. Perform the following to insert the Battery Pack into the pump or Remote Display/Charger:

a. Grasp the Battery Pack firmly.

b. Slide the Pack into the battery compartment on the rear of the Unit. Push in firmly until the pack snaps into place. The Battery Pack can be inserted when the Unit is either turned On or Off.

c. After the Unit is turned On, verify that the Battery Icon on the Main Display has the "X" removed and the Icon is filled or filling during the charge cycle.

Figure 6-1. Battery Installation

6.3 Charging the Battery Pack. After insertion of the Battery Pack, attach the Power Adapter to the Pump and the AC power source. The battery will charge automatically whenever the pump is connected to the AC power source as indicated by a visible Amber LED indicator on the Pump front panel. The Battery Pack can be inserted when the Pump is either turned On or Off.

After the Pump is turned On, verify that the Battery Icon on the Main Display has the "X" removed and the Icon is filled or filling during the charge cycle.

6.4 Removing the Battery Pack. Press in the Battery Pack latch located on the right side of the installed Pack. Grasp the Pack, and pull it outward from the Pump's Battery compartment. Another new or charged battery Pack can now be placed into the Pump. The Battery Pack can be removed when the Pump is either turned On or Off.

WARNING: The Battery Pack is slightly magnetic. Do not remove Battery Pack inside the MRI Scan Room.

Figure 6-2. Battery Removal

6.5 Testing the Battery Pack. The battery level is always evident on the Battery Icon when the Battery Pack is inserted into the Pump, and the Pump is "On". The operating capacity of the Battery Pack can also be tested without the use of the Pump. To examine the capacity level, depress the small button on the rear of the Battery Pack, as indicated on the Battery Pack Label. When pressed the Battery Level LED indicators will momentarily show the capacity (The indicators can range from five (5) L.E.D.s illuminated for fully charged, to one flashing L.E.D. illuminated for fully discharged).

Figure 6-3. Battery Test

6.6 Battery Charge Indicator. The Battery Gauge on the Main Display indicates approximate battery capacity remaining under current operating conditions. It is located in the upper portion of the display and is always visible. Check the remaining battery capacity when starting an infusion. The Battery Gauge updates continuously while infusing.

a. The battery recharges whenever the Pump and its Power Adapter is plugged into an AC power outlet, or optionally when the Battery Pack is inserted into the Remote Display Unit.

b. The system includes:

- A green/amber light that illuminates when Pump/Remote is plugged in to the AC power with the Power Adapter.
- An amber light that illuminates when Pump is charging the battery, green indicates charging current termination, and the Battery Pack is fully charged.
- Automatic switchover to battery power if Pump is unplugged or in the event of a power failure.

Note: This automatic switchover is not applicable in the Remote Display Unit, as it cannot operate on battery power.

6.7 Battery Low Indication. A Low Battery alert indicating that battery depletion is imminent, beginning at least 30 minutes prior to a depleted battery alarm. For best results, fully charge, discharge and recharge the battery before putting the Pump into service. Battery run time will be affected by the operating mode, rate, and back pressure.

Should the battery “smart power gauge” detect an over-discharge of one or more internal cells, the pump will provide a “BAD BATTERY” alarm condition. The pump should be turned off and on and recharged immediately to prevent battery damage. Restart/power cycle the pump and select Previous Patient to continue infusion.

CAUTION: If Pump is in storage and not used for more than 30 days, the battery pack should be removed.

6.8 Battery Power Gauge. Located at the top left of the informational display, this gauge is in the shape of a battery and provides a visual indication of the charge status of the battery. When the gauge is "full," then the battery is fully charged; when the gauge is "empty," then the battery is nearly depleted and the pump may not operate unless connected through the MRI Power Supply (pump only) to a hospital grade AC outlet. When the battery is removed, the gauge has an "X" placed inside it. If the Battery Operating time seems short, the battery gauge may require re-calibration, to accomplish this, perform the following:

a. Remove pump from clinical use. Set up pump to operate on battery power.

b. Operate pump until low power alarm occurs, continue to operate until the "DEAD BATTERY" alarm (capacity <2%) occurs.

c. Reconnect the pump to the 1120 MRI Power Supply or move the fully depleted battery to the Remote Display/Charger, and allow the pump battery to fully recharge. When in the pump recharging can occur during normal use if the pump is connected to its 1120 MRI Power Supply. The battery should recharge in less than nine (9) hours.

d. If battery life is still short, refer to qualified service personnel.

6.9 Battery Care and Maintenance:

6.9.1 Introduction. Over discharge, over charge and over current (short-circuit) are all conditions detected by the internal "smart power gauge" of the battery. These conditions all result in the battery shutdown (battery will not deliver power) until placed into charge. Over discharge can cause cells to outgas during subsequent charge cycles. Severe outgassing can result in the battery pack swelling. Replace any battery pack with visible signs of deformation or swelling.

6.9.2 1133 Battery Pack Maintenance Checkout Procedure.

The 1133 Battery Pack should be inspected anytime the pack is removed, or at least every 90 days for the following:

a. Battery Pack communicates with the Pump. This indicated by the Battery Icon being shown on the display of the Pump or Remote Display. Refer to Section 1.3.1 of this manual for Battery Icon description.

b. The Battery Pack holds sufficient operating charge capacity. This is indicated by allowing the Pump to operate on battery power for the recommended minimum time.

c. Battery Pack "Gas Gauge" indicator functions. These functions can be confirmed by performing the checks defined in Sections 6.5 and 6.6 above.

d. Physical Inspection of the Battery Pack case. Remove the Battery Pack from the Pump or Remote Display, and inspect for physical damage or signs of mechanical shock, cracked casing or swollen case.

e. Physical Inspection of the Battery Pack cell(s). Remove the Battery Pack from the Pump or Remote Display, and confirm that cells inside the Battery Pack are not swelling excessively, as noted by viewing internal cells from the edge of the Battery Pack case. Swollen cells that are greater than 8 mm thick, or cause the Battery Pack's plastic case to bulge indicate a failing battery pack.

Any failure of any of the above inspection criteria will require discontinuance of use and replacement of the 1133 Battery Pack.

6.10 Battery Pack Replacement. If the Battery Pack does not operate for the specified time after a full nine (9) hour charge cycle, replacement of the Battery Pack is recommended.

CAUTION: If placed into storage, to maintain battery life, assure that the battery pack remains charged above 25% (one battery segment is visible) as indicated by the "gas gauge" LED display.

6.11 Battery Pack Related Precautions.

The 1133 Battery Pack contains several lithium-polymer cells and an integral safety circuit. As these cells age, they can expand due to internal gas release, which is anticipated for this type of cell. However, if excessive expansion occurs, this can result in the battery case expanding (swelling), and possibly cause failure of the battery case, cells, or safety circuit. If this is observed, remove the Battery Pack from use and replace it as soon as possible.

The 1133 Battery Pack contains protective circuitry to prevent catastrophic battery failure. If the Battery pack is damaged, this protective circuitry may not prevent battery failure. Remove the Battery Pack from use if the Pack becomes damaged, or the potential for Battery Pack damage is suspected.

Do not use a damaged or swollen 1133 Battery Pack.

Avoid damage to the 1133 Battery Pack by impact, dropping, overheating, or mechanical abuse. Never compress, drop, shock, or strike the 1133 Battery Pack. Never use objects that could puncture the internal battery cells. Any of these actions can cause the battery cells to heat, smoke, or cause catastrophic battery failure, which could result in fire.

Do not attempt to disassemble the 1133 Battery Pack. Damage caused by disassembly or tool use can result in catastrophic battery failure, which could result in fire.

If the 1133 Battery Pack case begins to expand and/or swell, discontinue battery charging and use immediately, and replace the Battery Pack. Continued charging will cause further Battery Pack case expansion, with possible battery case fracture, and potential electrolyte leakage.

If the 1133 Battery Pack becomes damaged, avoid contact with the battery cell electrolyte. If the electrolyte contacts the skin or eyes, seek medical attention immediately.

If the 1133 Battery Pack shows sign of the battery case expanding (swelling), remove the Battery Pack from use and replace it as soon as possible. In extreme conditions, this swelling can cause the 1133 Battery Pack to become jammed or stuck within the 3860 Pump or 3865 Remote Display, and/or cause the Battery Pack plastic case to burst open. If this occurs, do not use tools that could cause damage to the internal battery cells. Refer to the 1125 Service Manual for removal under these conditions.

Under no circumstances should Battery Packs or the internal cells be incinerated as this can cause an explosion.

SECTION 7
PULSE OXIMETER

7.0 Introduction, Pulse Oximeter, 3860+.

The Model 3860+ MRI Infusion System includes a Digital Pulse Oximeter for use in simultaneously measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric and infant patients in an Magnetic Resonance (MR) environment. For this measurement, testing was performed in MR conditional environments at 1.5T and 3T. It is intended for spot checking and/or continuous monitoring of patients who are well or poorly perfused.

Informational tones communicate important information. Informational tones includes the pulse rate tone (which changes in pitch with SpO_2 values: higher tones for higher SpO_2, and lower tones for lower SpO_2).

References to “Masimo” in this manual shall imply Masimo Corporation. “Masimo” and “Masimo SET®” are registered trademarks of Masimo Corporation. This device is covered under one or more of the following U.S.A. patents: 5,758,644, 5,823,950, 6,011,986, 6,157,850, 6,263,222, 6,501,975 and other applicable patents listed at: www.masimo.com/patents.htm.

7.0.1 User Warnings and Precautions.

IMPORTANT:

The SpO_2 function turns off when the Sensor Fail or No Probe message is displayed and the Alarm has been silenced. The 3860+ Main Display will re-configure to the standard display (no SpO_2 displays visible). To re-activate the SpO_2, plug-in a working SpO_2 probe, or turn on the SpO_2 function on in the appropriate MENU screen.

Warnings

- USE ONLY Recommended SpO_2 Fiberoptic Sensors (Sensors containing electrical conductors will cause patient burns). Do not use cables or sensors that contain conductive wires.
- This device is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Oximeter readings of this device may be affected by the use of an electrosurgical unit (ESU).
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis, or as an apnea monitor.
- A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.
- Pulse oximeters require detection of a valid pulse to correctly determine SpO_2 and Pulse Rate values. This pump contains both audible and visual pulse indicators. The pulse waveform should be used an indication of interference. Normal (noise free) waveforms will appear as a smooth rhythmic waveform pattern.
- A "PROBE OFF" alarm or other alarms may not always indicate SpO_2 sensor dislodgement. Use the SpO_2 pulse waveform and other indicators to confirm proper SpO_2 operation and sensor placement.

- Use only recommended pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Iradimed Corporation's pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
- To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise obstruct any speaker openings**.**
- Sensor should be shielded from excessive extraneous incident light sources. Such extraneous light can cause reading error or pulse detection error.
- When audible alarms cannot be heard due to ambient noise, visible alarms must be used.
- The MRI SpO_2 Sensor uses a glass-fiber cable, which can become damaged with rough handling. The fiberoptic cable for this device is sensitive and must be handled carefully at all times. Do not use a damaged sensor. Do not flex or bend the cable at extreme angles to avoid breaking fiberoptic strands within the cable. Use proper care to not pinch or step on the cable. Take care to loop cable neatly for storage, as all bends should have larger than a 3 inch (7.5 cm) radius. Do not attempt to disconnect the fiberoptic cable from the Sensor's connector shell.
- The connector that attaches to the monitor must be kept outside the 10,000 Gauss line (or 1 Tesla magnetic field line) of the MR field and firmly secured to the monitor.
- The SpO_2 monitor can be used during defibrillation, but the readings may be inaccurate for a short time.

Precautions

- This equipment complies with IEC 60601-1-2:2001 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- If this device fails to respond as described, discontinue use until the situation is corrected by qualified technical professionals.
- The sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
- Do not gas sterilize or autoclave this device, sensors, or accessories.
- Do not immerse the SpO_2 patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof).
- This device has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the device may still interpret motion as good pulse quality.
- Inspect the sensor application site frequently at least every 1 hour to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors, sensor grips, and/or other methods may vary due to medical status or skin condition.
- Never use probe extender cables with a fiber optic sensor.
- Maximum SpO_2 probe temperature is dependant on skin temperature. No active heating of the probe can occur during use.

- Do not use caustic or abrasive cleaning agents on the unit or sensors.
- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.
- To prevent potential loss of monitoring or inaccurate data, remove any objects that might hinder pulse detection and measurement (e.g. blood pressure cuffs).
- This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:

  - the SpO_2 sensor attachment is too tight.
  - the patient is in cardiac arrest or is in shock.
  - excessive ambient light
  - excessive motion
  - electrosurgical interference
  - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
  - moisture in the sensor
  - improperly applied sensor
  - incorrect sensor type
  - poor pulse quality
  - venous pulsations
  - anemia or low hemoglobin concentrations
  - cardiogreen and other intravascular dyes
  - carboxyhemoglobin
  - methemoglobin
  - dysfunctional hemoglobin
  - artificial nails or fingernail polish
  - a sensor not at heart level.

- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
- Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.
- Review all Alarm limits to ensure they are appropriate for the patient.
- Use the MRidium SpO2 Sensor Grips to attach the probe to the patient. Do not use tape to secure the probe to the patient. Examine the sensor site at routine intervals to prevent any possible pressure damage or tissue necrosis during longer term monitoring sessions.

7.1 Installation.

Attach the Iradimed 1170 Fiber Optic SpO_2 sensor (see Section 7.4.1) to the SpO_2 Sensor Connector on the rear panel of the 3860+ IV Pump by squeezing the retainer clips (**See Figure 7.2**) to lock the probe into place. Verify that the sensor is firmly connected to the IV Pump. To remove sensor, squeeze retainer clips to open and gently pull probe from the connector.

7.2 Symbols, Displays, and Controls.

This section describes the displays, indicators, and controls for %SpO_2 Display.

7.2.1 SpO_2 Symbols.

The following symbols are used for the Pulse Oximeter parameter:

SpO_2 — Adjacent numbers represents the Pulse Oximeter parameter is operating, and are updated every 0.5 seconds.

% — Adjacent numbers represents the functional pulse oximeter value.

-- — Represents that no reliable SpO_2 or Heart rate value can be determined. This is also displayed when No Probe is attached.

Heart Rate Symbol: Adjacent numbers represent the pulse rate in beats per minute (BPM), and are updated every 0.5 seconds.

Filled Amount of symbol represents the pulse quality: Low perfusion or Low SIQ (half filled heart) or High quality (full heart).

PI xx.x — The Perfusion Index (PI) indicates the percentage of pulsatile signal to non-pulsatile signal (pulse strength), and ranges from 0.0% to 20.0%

The Pulse Waveform Display shows the acquired plethysmograph waveform. This waveform is scaled to the relative SpO_2 pulse strength. When no waveform is displayed, the SpO_2 signal is weak or missing, or the sensor has been detached.

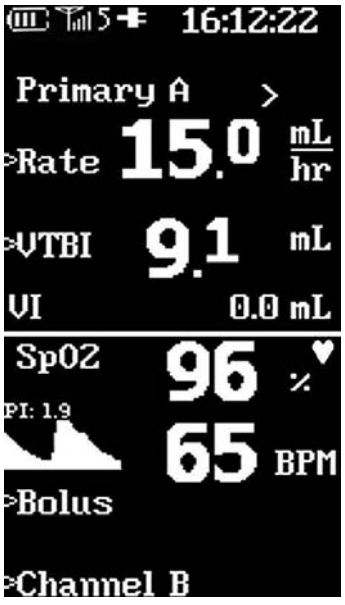


Figure 7-1. 3860+ Display w/SpO_2

7.2.2 Displays.

a. Pulse Oximeter (%SpO_2) Display

The %SpO_2 display is located on the top portion of the 3860 Display (see Figure 7-1), and is identified by the **%** and **SpO_2** symbol. This display shows blood oxygen saturation, from 0 to 99 percent. Refer to the Specifications in Section 7.11 for sensor accuracy information.

b. Pulse Rate Display

The pulse rate display is located on the top portion of the 3860+ Display (see Figure 7-1), and is identified as the numbers adjacent to the "Heart" symbol. This display shows the pulse rate in beats per minute, from 30 to 240 BPM. Refer to the Specifications in Section 7.11 for sensor accuracy information.

c. Pulse Rate Indicator

The pulse rate display is located on the top portion of the 3860+ Display, and is identified by the "Heart" symbol. This symbol pulses with the heart rate indicating pulse detection.

NOTE: The Pulse Rate "Flashing Heart" indicator is a reliable indicator of pulse detection, but the SpO_2 pulse waveform and audible pulse tones are better indications of pulse detection quality.

d. Pulse Quality Indicator (Heart icon).

This Pulse Quality Indicator fills or empties with each pulse to indicate pulse signal strength.

e. Sensor Alarm Indicator

The Sensor Alarm Indicator indicates when a sensor has become disconnected, has failed, or is not compatible with this monitor.

NOTE: The SpO_2 alarm indicators are latching alarms. The alarm silence button must be pressed to clear the alarm condition ("Probe Off" is non-latching).

f. Alarm and Alert Message Display

The Alarm and Alert Message display provides indications for alarms or troubleshooting problems.

NOTE: The SpO_2 Alarms and Alerts will not cause the infusion pump to stop the infusion. All SpO_2 Alarms and Alerts (except for the "No Probe" and "Probe Off" alerts) must have the alarm silence button toggled to clear the message.

g. The SpO_2 Alarms and Alerts Messages include:

Low SpO_2 The Low SpO_2 Alarm Indicator indicates when the SpO_2 value is below the Low SpO_2 Alarm setting. When the SpO_2 value returns above this value, the Alarm Silence button must be pressed to clear the alarm.

NOTE: There is no High SpO_2 Alarm indication on this product.

Hi HR The High Heart Rate Alarm Indicator indicates when the pulse rate value is above the High Heart Rate Alarm setting. When the pulse rate value returns below this value, the Alarm Silence button must be pressed to clear the alarm.

Low HR	The Low Heart Rate Alarm Indicator indicates when the pulse rate value is below the Low Heart Rate Alarm setting. When the pulse rate value returns above this value, the Alarm Silence button must be pressed to clear the alarm.
No Probe	The No Probe Alarm Indicator indicates when no SpO_2 sensor is connected at initial start up, or the sensor has been disconnected. This alarm indicator self-resets, once the probe sensor has be re-attached, and a valid SpO_2 and pulse rate have been detected.
Bad Probe	The Bad Probe Alert Indicator indicates when a sensor has become disconnected, has failed, or is not compatible with this monitor.
SpO_2 OFF	The SpO_2 OFF Alert Indicator indicates when the SpO_2 parameter has been turned off in the SpO_2 Menu. This is a momentary indicator, and will only be visible to acknowledge the SpO_2 parameter has been turned off.
SpO_2 Inop	The SpO_2 Inop Indicator indicates when the SpO_2 parameter has become inoperative due to a service-related issue. When this is visible, the Pump must be examined by a qualified service representative.
Probe OFF	The SpO_2 sensor is not properly attached to the patient. User needs to reattach sensor to the patient. This alarm indicator self-resets, once the probe sensor has be re-attached, and a valid SpO_2 and pulse rate have been detected.
Hi Light	Too much (high) light on patient (sensor). User needs to remove or reduce lighting, or cover sensor from light. Repositioning sensor may also help.
Noise	Outside signal or energy preventing SpO2 reading. User needs to remove outside interference.
Low SIQ (Low Signal IQ)	Low SpO_2 signal quality. Ensure proper sensor application. Move sensor to a better perfused site.
SEARCHING	Unit is searching for patient's pulse. If values are not displayed within 30 seconds, disconnect and reconnect sensor. If pulse search continues, remove sensor and replace on a better perfused site.

h. Alarm Indicator

During an active SpO_2 alarm, the audible alarm will sound, an alarm message will be displayed, and the Main Alarm red L.E.D. on the Pump will flash.

i. Alarm Silence Indicator

The Alarm Silence Indicator shows that the audible alarm is silenced for two minutes when it blinks. When an alarm is silenced, the audible alarm will be silenced for 2 minutes, and the Main Alarm red L.E.D. on the Pump will flash.

j. SpO_2 Menu

These keys access control for the upper and lower limits for alarm indications for SpO_2 and pulse rate measurements. When setting up the SpO_2 device, the dedicated SpO_2 MENU display allows the SpO_2 parameter to be enabled, the SpO_2 pulse tone to be enabled/disabled and also allows adjustments of the SpO_2 and Pulse Rate alarm limits, and specific SpO_2 settings. All adjustments must be made using the Up and Down keys.

7.3 Operator Verification.

NOTE: Before using the oximeter, please review all contraindications, warnings and cautions.

When the 3860+ MRI Monitor/Infusion Pump is first turned on, the system performs a brief initialization sequence for all parameters, including the SpO_2 monitor.

To verify that the 3860+ Pump's pulse oximeter is functioning properly, it is important to monitor SpO_2 and pulse rate readings. Use the following procedure to verify that the sensor is working properly.

1. Ensure that the 3860+ Pump is on, with the SpO_2 sensor connected.

2. Apply the pulse oximeter sensor (see sensor instructions for use).

3. Verify that a good SpO_2 reading is displayed, that a pulse rate value appears, and that the pulse strength indicator is active.

4. SpO_2 Alarm Test - Apply SpO_2 sensor to finger until SpO_2 value is observed. In the SpO_2 menu, adjust LOW SpO_2 (SAT) alarm limit below reading to activate the visual and audible alarm. Return alarm limit to original setting. Silence alarm and repeat for both LOW and HIGH heart rate limits to activate alarms. Confirm visual and audible alarms occur.

WARNING: This device is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

WARNING: Do not use a damaged oximetry sensor.

7.4 Operating the 3860+ Pulse Oximeter.

When operating the 3860+ Pump's pulse oximeter in the MR (magnetic resonance) environment, observe the following precautions:

WARNING: USE ONLY Recommended Fiberoptic Sensors (Sensors containing electrical conductors will cause patient burns). Do not use cables, sensors, or cable extenders that contain conductive wires.

Factory Defaults

The Model 3860+ Pump's pulse oximeter features the capability for Menu Setup and Factory Defaults.

The Factory Defaults, which include all adjustable parameters are set as indicated in the table below. These are the Model 3860+ Pump's pulse oximeter's default operating settings. The operating settings will revert back to the factory default limits 1 hour after the Pump has been powered off, or if a "New Patient" is selected.

Default alarm and operating settings can be selected within the SpO_2 Set-up menu.

Table 7-1

SpO_2 Feature	***Factory Default***	***Adjustment Options***	***Increment/ Decrement***
SpO_2 Measurement	Enabled	Enabled or Disabled	---
SpO_2 Tone	Enabled	Enabled or Disabled	---
Low SpO_2 Alarm Limit	85%	70-99	1%
High Pulse Rate Alarm Limit	200 BPM	75-240	1 BPM
Low Pulse Rate Alarm Limit	50 BPM	30-110	1 BPM

CAUTION: Review all limits to ensure they are appropriate for the patient.

NOTE: At power up or when "New Patient" is selected, the pump reverts back to the factory default alarms, with the SpO_2 tone enabled.

7.4.1 Probe Set-up and Use.

Model 1170 Adult/Pediatric Fiber Optic Pulse Oximeter Sensor

Iradimed Corporation Pulse Oximeter probes, are intended for spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate in a Magnetic Resonance (MR) environment.

NOTE: Because the fiber optic sensors and cables contain no conductive components, they can safely be placed on the patient's finger while inside an MR (magnetic resonance) environment.

7.4.2 Applying the Model 1170 Fiberoptic SpO_2 Sensor.

The MRidium MRI-SpO_2 Pulse Oximeter with Sensor Grip allows safe and convenient SpO_2 monitoring during infusion therapy in the MRI. A fiberoptic SpO_2 sensor is used to avoid potentially hazardous heating or image artifact during MR scans. The method of patient attachment uses a medical-grade silicone rubber Sensor Grip that allows easy and convenient attachment to the patient's hand or foot, and accommodates pediatric, adult, and infant patients with various size Grips.

Set up MRI-SpO_2 Pulse Oximeter with Sensor Grip

a. Connect the MRidium fiberoptic MRI-SpO_2 sensor to the SpO_2 connector located on the rear panel of the 3860+ Pump (**See Figure 7.2**).

Figure 7-2. Connecting the 1170 Fiberoptic Probe

b. Determine the proper size Sensor Grip (Pediatric, Adult, or Large). Follow the insertion guide (**See Figure 7.3**) to insert the fiberoptic ends into the Sensor Grip:

   (1). Insert the white ring/button into the smaller top Sensor Grip hole (the Grip number size, 1, 2, or 3, etc., is above this hole). This is the fiberoptic bundle with the light source for the sensor. Make sure the polished glass surface of this bundle points into the Grip where the finger will be positioned. You should be able to see the light when the Grip is opened.

   (2). Insert the black ring/button into the larger bottom Sensor Grip hole (the Grip number size is on the opposite side of this hole). This is the fiberoptic bundle for returning the SpO2 signal to the Pump. Make sure the polished glass surface of this bundle points into the Grip where the finger will be positioned.

c. Important: Both polished glass surfaces of the 2 SpO_2 Sensor bundles must face each other when inserted into the Sensor Grip. Improper insertion will cause failure in measuring SpO_2.

d. Open the Sensor Grip by squeezing its sides, and apply it to a desired finger, toe, or foot of the infant. The Grip number size (i.e. 1, 2, or 3, etc.) of the Sensor Grip should be positioned atop the nail bed, or fleshy part of the infant's foot (**See Figure 7.3**). Ensure the finger, toe, or foot of the infant is inserted fully into the Sensor Grip.

e. Verify that the Grip is comfortably positioned, and that the finger, toe, or foot is not being constricted to a degree that could harm the patient's finger, toe, or foot. If any unusual discoloration is seen where the Grip is positioned, select another position, or use a larger size Sensor Grip.

f. If possible, avoid the positioning of the MRI-SpO_2 sensor on the patient's limb(s) that could have blood flow affected by blood pressure cuffs, IV lines, or other sources of SpO_2 artifacts.

g. Verify the SpO_2 waveform is rhythmic and artifact-free, and the SpO_2 readings on the Pump match the patient's current assessment.

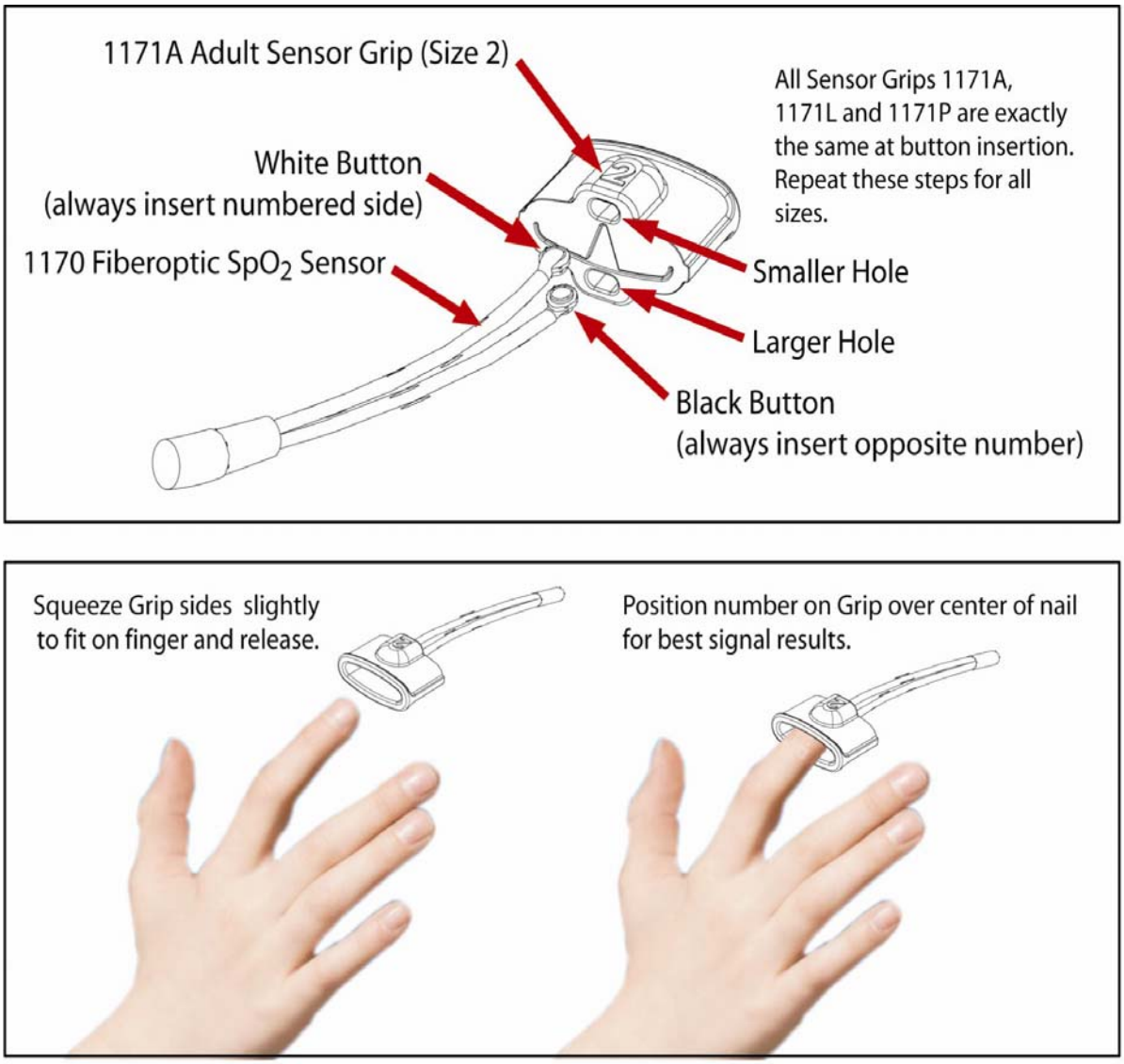

1171A Adult Sensor Grip (Size 2)
White Button
(always insert numbered side)
1170 Fiberoptic SpO2 Sensor
All Sensor Grips 1171A, 1171L and 1171P are exactly the same at button insertion. Repeat these steps for all sizes.
Smaller Hole
Larger Hole
Black Button
(always insert opposite number)
Squeeze Grip sides slightly to fit on finger and release.
Position number on Grip over center of nail for best signal results.

Figure 7-3. Applying the 1170 SpO_2 Sensor

h. Secure the position of the fiberoptic MRI-SpO_2 sensor cable in a parallel position to the patient to avoid any bends or kinks in the cable, and prevent any undue pulling of the sensor.

When moving the patient and/or the Pump, be careful to handle both the IV line and the MRI-SpO_2 sensor together to avoid entanglement and accidental disconnection of either of the attachments.

Note: If the sensor is not positioned properly, light may bypass the tissue and result in SpO_2 inaccuracies. Proper sensor application is critical for optimal performance.

WARNING: As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.

7.4.3 Verifying Operation of the Model 1170 Fiber Optic Sensor.

Allow at least one minute for the system to stabilize after the sensor has been properly applied and the patient is at rest. After stabilization, verify that the system is operating properly by:

- Ensuring that the sensor is applied to the finger as described above.
- Observing the Pulse Rate Indicator is flashing at a rate and rhythm corresponding to the patient's pulse for at least thirty seconds.
- If the following are observed, reposition the sensor or move the sensor to a different finger, following steps 1-3 of the above Section (Applying the Sensor).

  The Pulse Quality Indicator shows an inadequate pulse signal. If there is a sustained period of poor quality signals, this Pulse Quality indicator will prompt an alarm message.

  The Pulse Quality Indicator, pulse rate display, or SpO_2 display are functioning inconsistently.

If unable to verify operation, do not use the pulse oximeter. Contact Iradimed Corporation for assistance.

7.5 Probe Cleaning.

7.5.1 Cleaning the Model 1170 Fiberoptic Sensor and 1171 Sensor Grips.

- Unplug the sensor from the 3860+ before cleaning.
- Clean the sensor before attaching it to a new patient.
- Do not immerse the sensors in liquid of any kind.
- Do not use caustic or abrasive cleaning agents on the sensors.

The Model 1170 Fiberoptic sensor is reusable. Clean the sensor with a soft cloth dampened with a mild detergent or isopropyl alcohol using care not to pull or tug with excessive force. Ensure that all residue is removed. Do not pour or spray any liquids onto the sensor. Allow the sensor to dry thoroughly before reusing.

7.6 SpO_2 Alarms and Alerts.

The Model 3860+ Pump's pulse oximeter is equipped with audible and visual alarm indicators to alert the operator to provide immediate patient attention or to abnormal device conditions.

7.6.1 Patient and Equipment-Related Alarms.

SpO_2 patient-related alarms require immediate attention to the patient. If patient SpO_2 or pulse readings are equal to or above the upper alarm limit, or if they are equal to or below the lower alarm limit, the device will signal a patient-related alarm, indicated by flashing Alarm L.E.D.

These include the alarms listed in Table 7-1.

7.6.2 Watchdog Alarms.

Watchdog alarms indicate a hardware or software malfunction. When a watchdog alarm is activated, it can only be cleared by shutting down the Model 3860+ Pump's pulse oximeter. The watchdog alarm for the SpO_2 monitor will not interrupt the operation of the Infusion Pump, but a "SpO_2 Inop" message will appear to indicate this alarm.

When the infusion has been completed, powering down the Pump, and then re-starting the Pump should clear the SpO_2 Watchdog alarm. If the watchdog alarm cannot be cleared, remove power and contact your distributor or Iradimed Corporation's Technical Service.

7.6.3 Reviewing, Setting, or Changing Volumes and Alarm Limits.

WARNING: For patient safety, ensure that all alarm volumes are set appropriately, and are audible in all situations. Do not cover or otherwise obstruct the speaker opening on the rear of the Pump.

a. Alarm Settings Review.

Alarm Settings can be reviewed or adjusted using the following steps:

1. Ensure that the Pump is on.

2. Examine the limit you want to view or change using the SpO_2 Menu choices, and the limit is displayed:

- The current limit appears in the %SpO_2 setting area.
- The current setting appears in the Pulse Rate setting area.
- Continue to press the Menu Keys until the limit you want to change is displayed.

3. To change the displayed value, always press the Up or Down keys as needed.

4. Continue to press the appropriate Menu keys, or Cancel key, until the unit returns to normal operation.

CAUTION: Review all limits to ensure they are appropriate for the patient.

b. Silencing SpO_2 Alarms.

Pressing the Alarm Silence key silences an active alarm for two minutes.

NOTE: An SpO_2 alarm will not stop the Pump infusion.

c. The Audible Pulse Tone indicator can be turned off in the SpO_2 Menu, by selecting “Off” in the corresponding menu option.

IMPORTANT: If the SpO_2 tone has been disabled, it is automatically enabled at pump power up.

IMPORTANT: The SpO_2 audible tone operation on the 3865 Remote Display/ Charger always matches that on the pump. The audible tone can’t be separately enabled or disabled on the 3865 Remote Display.

7.7 SpO_2 Menu Choices.

1. SAT (SpO_2) Low Lim: -Allows adjustment of Low SpO_2 Alarm Limit
2. HR Hi Lim: -Allows adjustment of High Heart Rate Alarm Limit
3. HR Low Lim: -Allows adjustment of Low Heart Rate Alarm Limit
4. SpO_2 Enabled/Disabled -Allows user to disable SpO_2 Function. SpO_2 function can be re-enabled by toggling this key.
5. SpO_2 Tone ON/OFF -Allows user to disable or enable pulse Tone/ Beep that occurs with pulse detection. The volume of the tone is adjusted using the Alarm Volume setting.

7.8 SpO_2 Troubleshooting.

Problem	Possible Cause	Possible Solution
Unable to obtain a pulse indication on the display.	The patient pulse strength is indiscernible or perfused poorly.	Reposition the finger or insert a different finger, and keep the sensor motionless for at least 10 seconds. Warm the patients finger by rubbing or covering with a blanket.
	Circulation is reduced because of excess pressure on the sensor (between the sensor and a hard surface) after inserting finger.	Position the sensor at a different site Allow the hand to rest comfortably without squeezing or pressing the sensor on a hard surface.
	The finger is cold.	Warm the patients finger by rubbing or covering with a blanket.
NOTE: In some instances, patient perfusion may be inadequate for pulse detection.	The sensor is applied incorrectly.	Position the sensor at a different site. Apply the sensor correctly.
	There is possible interference from one of the following sources: (1) arterial catheter, (2) blood pressure cuff, (3) electrosurgical procedure or (4) infusion line.	Reduce or eliminate any interference. Make sure that the sensor is not placed on the same arm being used for other patient therapies or diagnostics (e.g. blood pressure cuff).
	The red LED is not lit in the finger insertion area.	Ensure the sensor is securely attached to the 3860+ pump. Check the sensor for any visible signs of deterioration contact Iradimed Corporation Technical Service.
	Sensor bundles are not positioned properly inside the sensor grip.	Ensure the polished glass surface of the probe bundles are placed toward the center of the sensor grip. Ensure both bundles are pushed fully inside the grip. Ensure sensor holes in grip are clear of any debris.

Problem	Possible Cause	Possible Solution
Frequent or steady low pulse quality indication.	There is excessive ambient light.	Shield the sensor from the light source.
	The SpO_2 sensor is applied to a polished or artificial fingernail.	Apply the sensor to a finger without artificial or polished nails. Position the sensor at a different site.
	The red LED is not lit in the finger insertion area.	Ensure the sensor is securely attached to the 3860 Pump Check the sensor for any visible signs of deterioration. Contact Iradimed Corporation Technical Service.
	Excessive patient motion.	Reduce patient motion.
A dash (---) appears in the SpO_2 display.	An inadequate signal from the finger is being detected.	Reposition finger or insert a different finger, keeping sensor motionless for at least 10 seconds.
	The finger was removed from the sensor.	Reinsert the finger and keep the sensor motionless for at least 10 seconds.
	The SpO_2 function of the 3860+ Pump is not working.	After the infusion has been completed, turn the pump off, and check all connections, and retry. Contact Iradimed Technical Service.
An error code appears in the display area.	The SpO_2 function of the 3860+ Pump encountered an error.	After the infusion has been completed, turn the unit off and then back on again to remove the error code. If the error persists, disconnect all power, and then reconnect the power and turn the unit back on. If the error still persists, note the error code and contact Iradimed Corporation Technical Service.

Problem	Possible Cause	Possible Solution
The unit is in Alarm mode but no audible alarms can be heard.	The 2 minute Alarm Silence button is activated.	Press the Alarm Silence key to re-engage alarm volume, or wait for two minutes. After two minutes, alarm tones will automatically re-engage.
	Audible volume set too low to be heard.	Adjust volume through the Menu Set-up screen.
SpO_2 probe can't be removed from pump.	Operator must release spring loaded latches to remove SpO_2 sensor from the pump.	Grasp and squeeze the 2 spring loaded latches on either side of SpO_2 sensor connector to release the SpO_2 probe from pump.

7.9 SpO_2 Parts and Accessories.

The following Iradimed Corporation accessories function with the Model 3860+ Pump's pulse oximeter. Detailed information regarding specified sensor use (patient population, body/tissue, and application) can be found in the respective sensor instructions.

Model Number /Description

Pulse Oximeter Reusable Sensors

1170 Adult/ Infant/Pediatric Fiber Optic Pulse Oximeter Sensor

Sensor Accessories

1171A Adult Finger Grip

1171P Infant/Pediatric Grip

1171L Adult Large Finger Grip

1172 IV Pole hanger for SpO_2 Sensor Cable

WARNING: The use of accessories, sensors, and cables other than those listed in this manual may result in increased electromagnetic emission and/or decreased immunity of this device.

WARNING: Use only recommended pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for the MRI pulse oximeter. Using other manufacturers' sensors can result in improper pulse oximeter performance.

7.10 SpO_2 Testing Summary.

SpO_2 accuracy, and low perfusion testing were conducted using the Masimo SET Technology and sensors with Masimo optical sources and receivers. The Iradimed Corporation fiberoptic MRI SpO_2 sensors utilize the same Masimo active optical components.

Masimo Rainbow SET technology (using sensors with Masimo optical sources and receivers) has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

Masimo Rainbow SET technology (using sensors with Masimo optical sources and receivers) has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

The test subjects' demographics for the validation study included: 58% male and 42% female subjects; 58% light-skinned, 25% medium-skinned, and 17% dark-skinned pigmented subjects; with ages ranging from 21 to 35 years; with weights ranging from 57 to 90 kg.

Masimo Rainbow SET technology (using sensors with Masimo optical sources and receivers) has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

7.11 Specifications.

Oxygen Saturation Display Range: 0 to 99% SpO2

Pulse Rate Display Range: 30 to 240 pulses per minute (BPM)

SpO_2 Accuracy (Arms)[a]:

FO Sensor ±2% (full scale) over 70-100%

Pulse Rate Accuracy (Arms)[a]:

No Motion ±3 BPM over 30-240 BPM

Low Perfusion ±3 BPM over 30-240 BPM

a.) ±1 Arms represents approximately 68% of measurements

SpO_2/Pulse Rate Response Time: < 10 seconds

Measurement Wavelengths and Output Power[b]:

Red: 660 nm @ 0.8 mW maximum average

Infrared: 910 nm @ 1.2 mW maximum average

b.) This information is especially useful for clinicians performing photodynamic therapy.

SpO_2 Temperature (Operating): 0^o to $+40^o$ C (32^o F to 104^o F)

Temperature (Storage/Transportation): -30^o to $+50^o$ C (-22^o F to 122^o F)

SpO_2 Humidity (Operating): 10 to 90% noncondensing

Humidity (Storage/Transportation): 10 to 95% noncondensing

SpO_2 Altitude (Operating): Up to 12,000 meters (40,000 feet)

SpO_2 Sensor Accuracy

SpO_2: ±2% (full scale) over 70-100% (A_{rms}*).

Pulse Rate Accuracy: ±3 BPM over 30-240 (BPM)

*±1 A_{rms} represents approximately 68% of measurements.

Probe Compliance:

This product complies with ISO 10993-1.

Probe Warranty:

The 1170 is warranted for 90 days from delivery.

SpO_2 Sensor Type: Fiberoptic SpO_2 Probe

SpO_2 Sensor Length: 7.5 ft. (230 cm)

NOTE:

The Masimo SET technology used in the MRidium 3860+ System has been validated in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor.

7.12 The Masimo Set® Principles of Operation.

The Masimo SET® MS pulse oximeter is based on three principles:

1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).

2. The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).

3. Arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse.

The Masimo SET® MS pulse oximeter as well as traditional pulse oximetry determines SpO_2 by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photodetector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelengths, 660 nm and 905 nm:

$$S(660) = AC(660)/DC(660)$$

$$S(905) = AC(905)/DC(905)$$

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

$$R = S(660)/S(905)$$

This value of R is used to find the saturation SpO_2 in a look-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The Masimo SET® MS board pulse oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. MS board decomposes S(660) and S(905) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

$$S(660) = S1 + N1$$

$$S(905) = S2 + N2$$

$$R = S1/S2$$

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO_2 in an empirically derived equation into the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The above equations are combined and a noise reference (N') is determined:

$$N' = S(660) - S(905) \times R$$

If there is no noise N' = 0: then S(660) = S(905) x R which is the same relationship for the traditional pulse oximeter.

The equation for the noise reference is based on the value of R, the value being seeked to determine the SpO_2. The MS board software sweeps through possible values of R that correspond to SpO_2 values between 1% and 100% and generates an N' value for each of these R-values. The S(660) and S(905) signals are processed with each possible N' noise reference through an adaptive correlation canceler (ACC) which yields an output power for each possible value of R (i.e., each possible SpO_2 from 1% to 100%). The result is a Discrete Saturation Transform (DST™) plot of relative output power versus possibleSpO_2 value as shown in the following figure where R corresponds to SpO_2 = 97%:

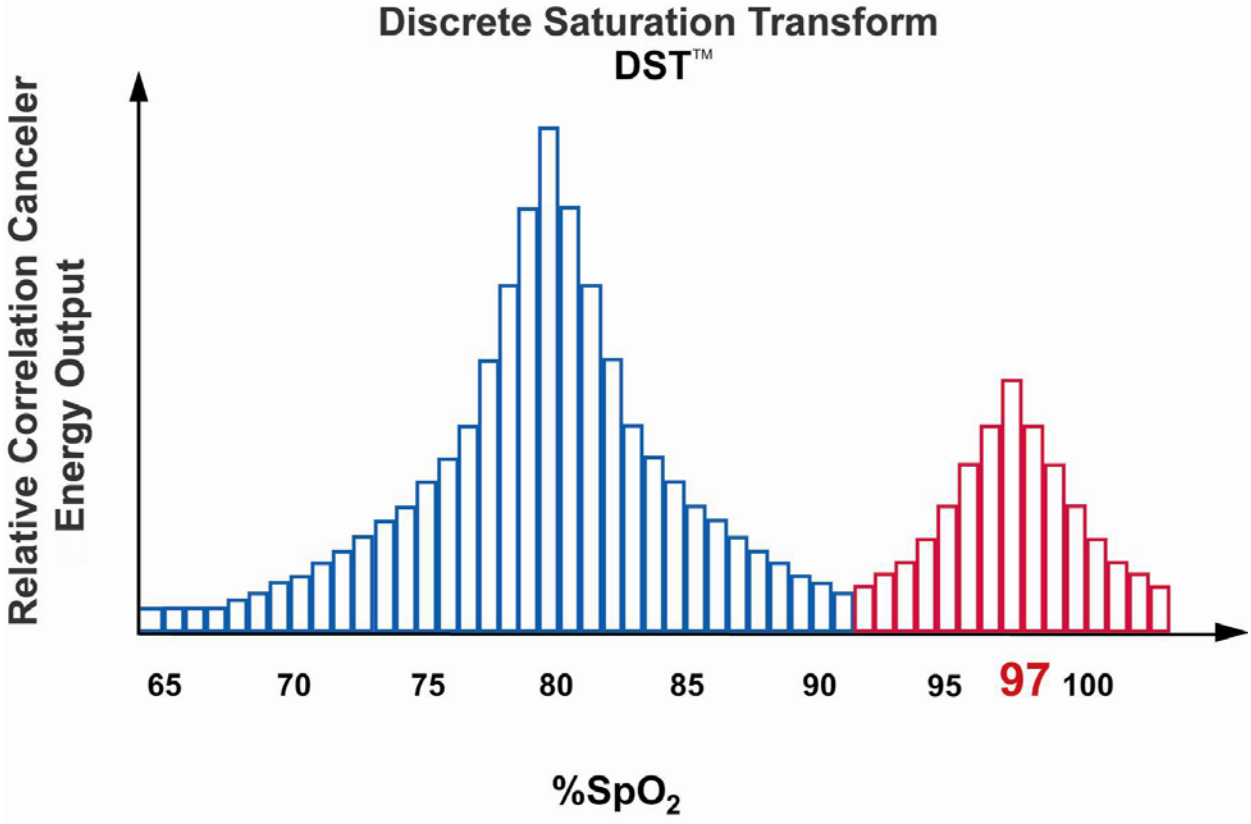


Figure 7-4. Saturation Charting.

The DST plot has two peaks: the peak corresponding to the higher saturation is selected as the SpO_2 value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The MS board SpO_2 therefore corresponds to a running average of arterial hemoglobin saturation that is updated every two seconds.

SECTION 8

DOSE ERROR REDUCTION SYSTEM (DERS)

PART NUMBER 1145

8.0 Dose Error Reduction System.

8.1 Introduction:

The Model 3860+ MRI Infusion System can be expanded to include an optional Dose Error Reduction System (DERS) feature (Part Number 1145) that allows user facilities the ability create a unique Drug Library of user specified drug names, and also to establish nominal values and limits for the Dose, Concentration, Weight and Time for specified infusion protocols.

The DERS option provides the following features:

• A user programmable drug library memory card for storage of the specific infusion protocols established by the hospital facility. This library is accessed using the pump's Dose Rate Calculator Menu.

• The drug library card supports 30 separate user-programmed infusion protocols for either primary and/or primary/bolus infusions, retrievable by drug/protocol name.

• User-programmed nominal starting values for: Dose, Concentration, Time.

• User-programmed hard limits (maximum and minimum) and soft limits (high and low limits that require a user confirmation to exceed) for: Dose, Concentration, Time, and patient Weight.

• Status indicators denoting when the Drug Library LIB is active, and when infusion protocol parameters are operating outside designated "soft limits". These limits are programmed by the user as the 'soft' high and low limits that require a user confirmation to exceed.

• The infusion's Dose is displayed on the running display screen, and can be adjusted directly (titrated) on the running screen (Dose Mode display).

• Remaining Time for an active infusion is displayed on the running screen.

• I/O port communication for outputting Drug Library entries to external devices for archiving the Drug Library entries.

IMPORTANT: It is recommended to revalidate any DERS Library whenever the MRidium™ infusion pump software is changed.

8.2 Installation.

WARNING: For safe operation, the optional Dose Error Reductions System (DERS) feature requires MRidium 3860+ Pump software version 3.5.1 or higher. Refer to the Installation instructions in the PN 1145 DERS Software Update Kit's SD005 Instructions for loading the pump software (if necessary), and installing the DERS Drug Library Card.

Note: The optional Dose Error Reductions System (DERS) Drug Library Card must be programmed by the hospital/facility Drug Library control personnel prior to installation. Once the programmed DERS Library Card has been installed in the 3860+ MR IV pump, only those drugs, concentrations, and dosing units established by your facility are accessible via the Dose Rate Calculator. Consult with your facility's staff for drug library programming which is performed in the service mode and not recommended for end user access.

Installing or Removing DERS Library programming card: (to be performed by a qualified service technician outside the MRI Magnet Room)

a. Turn OFF power to the MRidium™ 3860+ Pump.

b. Remove the small poly bag from the 1145 update kit which contains the Black Aluminum SD Card retainer clip and the #4 screw. This part will be used as a safety guard once the programming card is in place.

IMPORTANT: The hardware provided is non-magnetic. Do not substitute any parts (clip or screw), that may be magnetic, and not safe for use in the MRI.

c. Insert the AM05 MRidium™ DERS Library Card from the kit into the Memory Port on the back of the pump. Insert with the card label facing DOWN (diagonal cut corner of the card facing RIGHT). Verify that the Library Card is firmly connected in the IV Pump. Refer to **Image 8-1** and **Image 8-2** below for Memory Port location:

Image 8-1

Image 8-2

d. With AM05 card in place, using a Phillips head screw driver, place the SD Card Retainer clip directly over the card, aligning with screw hole to left of SD card slot. A small tang on the right side of the clip should align inside the right edge of the card slot. Secure the screw. This will prevent accidental removal of card during use. Refer to the **Image 8-3** below:

Image 8-3

e. Consult Facility Drug Library control personnel for specific programming.

f. Removal of the DERS Drug Library Card requires the removal of the SD Card Retainer clip using a Phillips head screw driver, and pressing in on the SD Card to release it from the connector. If the Pump is to be used without the DERS Drug Library Card, either reinstall the SD Card Retainer clip, or store it for future use.

NOTE: A DERS Drug Library Card is not required for the Remote Display unit. However, the Remote Display unit must also have the MRidium 3860 Pump software version 3.5.1 or higher to communicate with a Pump with DERS.

8.2.1 Verifying Operation of the DERS Drug Library Card.

Perform the following steps to verify the DERS Drug Library card operation:

a. Ensure that the DERS Drug Library Card is installed in the memory card port of the MRidium™ 3860+ Pump.

b. Turn on the MRidium™ 3860+ Pump. Select the NEW PATIENT option. The Pump will sound a three-tone sequence to indicate the DERS Library Card is active.

c. Press the MENU control key.

d. Press the DOSE RATE CALC. (A or B) soft key. "Dose Rate Calc. B" message will only be visible if the SidecarTM (Channel B) has been connected.

e. Observe that the Dose Rate Calculation Menu (**See Figure 8-1**) displays the first drug name of the designated hospital drug library. All the other drugs in the drug library on DERS Library Card the can be viewed using the UP/DOWN keys. This list continues until the first drug name is seen again (i.e. wraps around).

f. When an infusion is started, the ~~LIB~~ indicator will be seen adjacent to the drug name and Dose on the ~~runn~~ing screen.

8.2.2 Removal of the DERS Drug Library Card.

Perform the following steps to remove the DERS Drug Library card:

1. Remove the 1145 DERS Library card (AM05) from the 3860 Pump using the following instructions:

   NOTE: Perform this procedure outside the MRI area:

   a. Turn OFF power to the MRidium™ 3860+ pump.

   b. On the back of the pump, use a Phillips head screwdriver to remove the #4 screw holding the Black Aluminum SD Card retainer clip (safety guard) in position. Refer to the Figure 8-3 for SD Card retainer clip location.

   c. Momentarily press in the AM05 MRidium™ DERS Library Card further into the Memory Port and release it to eject the card from inside the pump. Grasp and remove the DERS Library Card from the pump. Refer to the Figure 8-1 for Memory Card Port location.

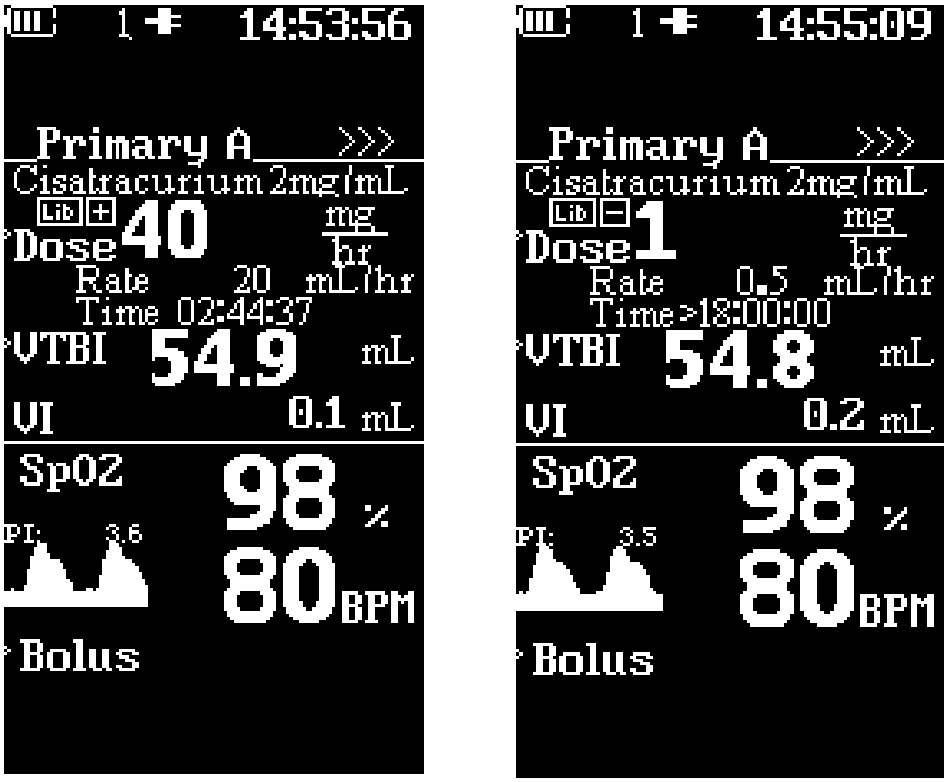
   d. Store the DERS Library Card and the SD Card Retainer clip and screw in a safe place until the DERS Library card is returned to use.

2. Turn on the MRidium™ 3860+ Pump. Select the NEW PATIENT option. Press the MENU control key. Observe that the Dose Rate Calculation Menu (refer to Figure 4-7) displays “Drug ?” as the first drug name.

3. Notify the clinical staff that the DERS Library has been disabled. They may need to review their clinical protocols until the DERS Library is returned to use.

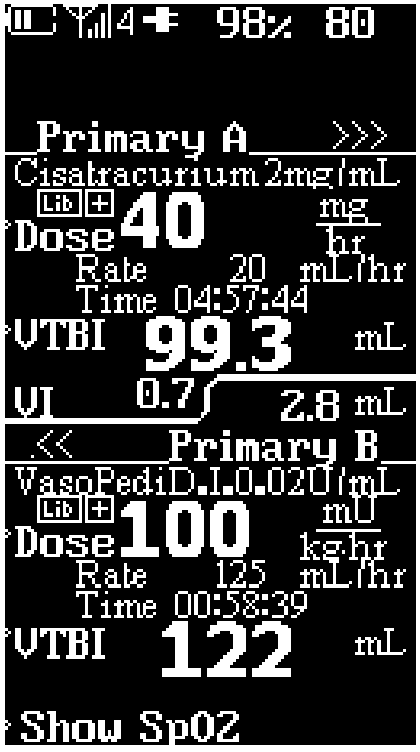
8.3 DERS Displays .

8.3.1 DERS Informational and Running Screen Displays .



DERS Running Screen with SpO_2

Figure 8-1. Primary Screen with DERS Settings



DERS Dual Channel running screen

Figure 8-2. Primary A & B running screen with DERS

8.3.2 DERS Menu Choices - Reviewing, Setting, or Changing Drug Library Limits:.

a. The optional Dose Error Reductions System (DERS) Drug Library Memory Card can only be programmed or changed by the hospital/ facility Drug Library control personnel prior to installation. Refer to the 1125 Service Manual for the Drug Library Card programming procedure.

b. With a programmed DERS Library Card, users can set the following parameters within the following limits:

Drug Name - The drug name is programmed on the Library Card, and can't be changed by the user. Only the hospital/facility Drug Library control personnel can make these changes

Dose (Numeric settings) – The programmed default numeric setting is displayed for every new infusion. Numeric settings can be set within the specified minimum and maximum limits (i.e. hard limits) programmed on the Library Card. An over-ride prompt is displayed if the numeric setting is greater than, or less than, the programmed High and Low setting (i.e. soft limits) programmed on the Library Card. The programmed limit is also momentarily displayed with the prompt. If no limits are programmed, the full range of values can be used, dependent on the Dose Units selected (refer to Table 3 in Appendix A for the full range of settings).

NOTE:

In software revision 3.2.9 and higher, the Dose Rate Calculator Bolus feature now defaults the Bolus Dose Units to "mL" so that the initial Bolus setting choices are Volume and Time for any Bolus infusion, rather than the Rate & Volume setting choices. With these new default settings, the Time default value is set to 1 minute. All other Bolus Dose Units are still available (e.g. mcg/kg/ hr, mcg/kg, etc.), if appropriate, for the Dose Rate Calculator during programming.

Dose (Units settings) - Units settings (e.g. mg/kg/min, units/kg, etc.) are programmed on the Library Card, and can't be changed by the user. Only the hospital/facility Drug Library control personnel can make these changes.

Concentration (Numeric and Units settings) - The Concentration value is programmed on the Library Card, and can't be changed by the user. Only the hospital/facility Drug Library control personnel can make these changes.

Weight (Numeric and Units settings) - Numeric settings can be set within the specified minimum and maximum limits (i.e. hard limits) programmed on the Library Card. An over-ride prompt is displayed if the numeric setting is greater than, or less than, the programmed High and Low setting (i.e. soft limits) programmed on the Library Card. The defined limit is also momentarily displayed with this prompt. If no limits are programmed, the full range of values can be used (refer to Table 3 in Appendix A for the full range of settings). The Units settings are fixed at “kg”.

Rate (Numeric and Units settings) - Numeric settings are set within the specified range of the Pump (0.1 to 1400 mL/hr), and are determined by the Dose Rate calculator, (i.e. can’t be set by the user). The Rate Units settings are fixed at “mL/hr”.

VTBI (Numeric and Units settings) - Numeric settings can be set within the specified range of the Pump (0.1 to 999 mL). The Units settings are fixed at “mL”.

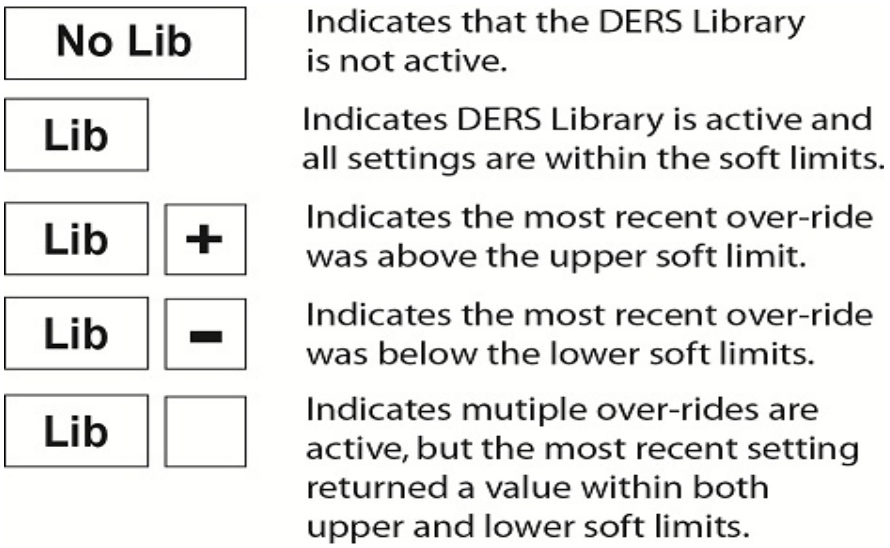
Time (Numeric and Units settings) – If programmed with a default numeric setting, this setting is displayed for every new infusion. Time is only a selection on infusions using timeless dose units (e.g. mcg/kg, mU/kg, etc.). Numeric settings can be set within the specified minimum and maximum limits (i.e. hard limits) programmed on the Library Card. An over-ride prompt is displayed if the numeric setting is greater than, or less than, the programmed High and Low setting (i.e. soft limits) programmed on the Library Card. The programmed limit is also momentarily displayed with the prompt. If no limits are programmed, the full range of values can be used (refer to Table 3 in Appendix A for the full range of settings).

Parameter High and Low Limits (Soft Limits) –The soft limit values are programmed on the Library Card, and can’t be changed by the user. These parameter limits apply to the Dose, Weight, and Time (if applicable) of the programmed drug. An over-ride prompt is displayed if the numeric setting is greater than, or less than, the programmed High and Low setting (i.e. soft limits) programmed on the Library Card. The defined limit is also momentarily displayed with this prompt. The user must press ENTER to accept the parameter above or below the programmed limit for the Infusion to begin. Otherwise, the user should press CANCEL (No) to cancel the parameter change. If no entry is made, the change will cancel automatically in 10 seconds. If no soft limits are programmed, the full range of values can be used, dependent on the Dose Units selected (refer to Table 3 in Appendix A for the full range of settings). Only the hospital/facility Drug Library control personnel can change these settings.

Parameter Maximum and Minimum Limits (Hard Limits) – The hard limit values are programmed on the Library Card, and can't be changed by the user. These parameter limits apply to the Dose, Weight, and Time (if applicable) of the programmed drug. The defined limit is also momentarily displayed with this prompt. Infusion can't be started with the existing setting for this parameter. Modify the selected parameter to within the acceptable limits to allow the infusion to proceed. If no hard limits are programmed, the full range of values can be used, dependent on the Dose Units selected (refer to Table 3 in Appendix A for the full range of settings). Only the hospital/facility Drug Library control personnel can change these settings.

8.3.3 DERS Symbols/Indicators.

The following indicators are used to denote specific functions of the DERS:


No Lib
Indicates that the DERS Library is not active.
Lib
Indicates DERS Library is active and all settings are within the soft limits.
Lib +
Indicates the most recent over-ride was above the upper soft limit.
Lib −
Indicates the most recent over-ride was below the lower soft limits.
Lib
Indicates mutiple over-rides are active, but the most recent setting returned a value within both upper and lower soft limits.

8.4 Starting an Infusion with DERS Drug Library.

8.4.1 Starting a Primary and/or Bolus infusion with DERS Drug Library.

The DERS Drug Library feature is used to provide user-set parameters for the infusions for either Channel A or B, and is accessed using the Menu key. Initial user programmed infusion parameters in the Drug Library are shown in Dose Rate Calculator Menu display, and the user must enter any remaining values for the parameters before an infusion can begin. The user can only change certain values dependent on the programmed drug library. In this mode, the Drug Library must be turned on in the Service Mode.

Perform the following steps to select the DERS Dose Rate Calculator with Drug Library Calculator:

a. Press the MENU control key.

b. Press the DOSE RATE CALC. (A or B) soft key. "Dose Rate Calc. B" message will only be visible if the SidecarTM (Channel B) has been connected.

c. Observe that the first drug name is highlighted.

d. Use the up and down arrow keys to select the drug from the Library Card.

e. Press Enter.

f. Observe that the Dose Rate Calculation Menu will be displayed with the word "Primary" highlighted.

g. Use the up and down arrow keys to select Primary or Bolus.

h. Press ENTER or the DOSE soft key. Observe that the Dose value is highlighted. The user pre-set Dose value should be seen, with the appropriate Dose units. Use the numeric keys (or the up and down arrow keys) to select the desired Dose value.

i. Press ENTER, or the DOSE soft key. Observe that the units are highlighted and cannot be changed from the user pre-set value on the Library Card.

j. Press ENTER or the CONC (concentration) soft key. Observe that the Concentration value and units cannot be changed from the user pre-set value on the Library Card.

k. Press ENTER or the WEIGHT soft key.

l. Observe that the Weight value is highlighted. Use the numeric keys (or the up and down arrow keys) to enter the patient's weight in kg.

NOTE: If the patient weight is in pounds, divide that value by 2.2 to get weight in kilograms.

m. Press the appropriate VTBI, or Time (if displayed) soft key.

n. Observe that the selected value is highlighted.

o. Use the numeric keys (or the up and down arrow keys) to select the value. Press ENTER to complete the selection.

p. If necessary, use the up and down arrow keys to select the Bolus. Repeat the above steps g. though o. to select the Bolus parameters.

q. The rates for both the Primary and Bolus (if applicable) will automatically be calculated and the Ready to Start (A) or (B) prompt will appear.

r. Verify all entered values before starting infusion.

s. Press the START/STOP Channel control key. The Main running screen will display with the correct parameters from the Dose Rate calculation screen with the Dose value displayed between the Rate and VTBI parameters.

NOTE: If the Bolus infusion protocol for a specific drug has not been programmed on the Drug Library Card, the numeric values will default to zero (0), and the Dose units will default to units based on the Concentration units for the specific drug. The Bolus Concentration values will be the same as used in the Primary infusion protocol.

NOTE: During the Dose Error Reduction System (DERS) Library Card programming, the Bolus feature for each programmed drug now defaults to “disabled”, so that if no Bolus is programmed on the Library Card, no Bolus capability is provided during clinical use for this medication.

8.5 Other Programming with DERS Drug Library.

All other features related to infusions with DERS Drug Library are identical to that with the standard 3860+ Pump. Refer to Section 4 for this information.

8.6 Data Retention.

The pump program settings and option selections (including Drug Library over-rides) are retained in nonvolatile memory. If the pump has been turned off for longer than one (1) hour, delivery settings are cleared.

The History Log data, which stores a comprehensive range of the pumps operational information, is retained indefinitely on a FIFO (First In - First Out) basis. The History Log holds approximately 3,000 to 5,000 entries and alarms. It can be downloaded from the Pump into a computer to review. This is accessed in the Service mode. (Please see Service Manual 1125 for more details).

APPENDIX A

SPECIFICATIONS

GENERAL SYSTEM REQUIREMENTS	
General Features	Volumetric Infusion Pump for use in the MRI
Pump Dive Mechanism	Linear Peristaltic
Number of Pump Channels	2
User Event Log	Non-volatile memory retains each operating step and alarm - up to 5000 entries
ELECTRICAL CHARACTERISTICS	
HI/LO Line Voltage Requirements	100 to 240 VAC +/-10%, 50/60 Hz
Power Sources Available	Internal battery power with separate AC charger/power supply
Power Consumption	< 15 Volt-Amperes @ 120 VAC nominal at 125 mL/hr (<100 VA maximum during charging)
Battery Type	Rechargeable Lithium Polymer Pack, 14.8 v at 5.8 Ah
Battery Capacity	> 12 Hours at 125 mL/hr Rate
Battery Charge Time	< 9 hours to 95% capacity
Battery Cycle Life	Typical Life > 200 charge/discharge cycles
Patient Leakage Current	< 10 uA RMS
Chassis Leakage Current	< 100 uA rms; < 300 uA RMS (Single Fault)
Chassis Ground Impedance to Earth Ground	< 0.1 ohms (with power supply)
MECHANICAL CHARACTERISTICS	
Dimensions D x W x H	6 x 8 x 9 Inches (15.25 x 20.3 x 22.9 cm)
Total Weight	10 LBS (4.5 Kg); 11.5 LBS (5.2 Kg) with Battery.
Operating Temperature Range	$+5^{O}$ to $+40^{O}$ C
Storage Temperature Range	-40^{O} TO $+70^{O}$ C
Operating Relative Humidity Range	0% to 80% RH, non-condensing
Storage Relative Humidity Range	0% to 95% RH, non-condensing
Pole Clamp Mounting (Pole Diameter) Range	1 inch to 1.5 inch (25 to 38 mm) diameter

PERFORMANCE CHARACTERISTICS	
Infusion Pump Performance	
Flow Rate Range - 0 to 100 mL/hr	0.1 to 99.9 mL/hr in 0.1 mL/hr increments
Flow Rate Range - > 100 mL/hr	100 to 1400 mL/hr in 1 mL/hr increments
Flow Rate Display Range	0.1 to 99.9, 100 to 1400 mL/hr
Flow Rate Accuracy	within 5% (for 0.1 to 0.9 mL/Hr, within 10%)
Primary Volume To Be Infused (VTBI) Range	0.1 to 99.9, 100 to 999 mL
Secondary Volume To Be Infused (VTBI) Range	0.1 to 99.9, 100 to 999 mL
Total Volume Infused (VI) Range	0.1 to 99.9, 100 to 9999 mL
Keep Vein Open (KVO) Rate Range	adjustable, 1 to 5 mL/hr, or set rate, whichever is lower.
Keep Vein Open (KVO) Default Rate	1 mL/hr
Patient Line (downstream) Back-Pressure Range	+300 to -100 mmHg
Downstream (proximal) Occlusion Detection Range	1 to 10 PSI (6.9 to 68.8 kPa), user-adjustable
Occlusion Detection Mechanism	Two separate (upstream & downstream) semiconductor force sensors
Occlusion Pressure Measurement Range	1 to 10 PSI (6.9 to 68.8 kPa), with 0.2 PSI resolution
Occlusion Pressure Measurement Accuracy	< 2 PSI (13.8 kPa), or within 10% of setting, whichever is greater.
Occlusion Detection (no flow) Time	typically <30 sec, dependent on selected Flow Rate, 55 min max. @ 1 mL/Hr
Occluded I.V. Line bolus volume (25 mL/Hr to 10 PSI occlusion)	0.7 mL max.
Air-in-Line Detection Method	Ultrasonic bubble detector
Air-in-Line Detector Threshold(s)	> 100 uL
Liquid Source height limits	+100 to -50 cm relative to pump center
Calibration units of measure	mL/hr, mL, Volts, PSIG, %SpO_2 and BPM
Audible Alarm Range (at 1 Meter)	Minimum: 65 dBA Maximum: > 85 dBA
MRI Performance	
MRI Magnet Compatibility	0.2 to 3.0 Tesla MRI Systems
MRI Larmor Frequency Interference	No interference at compatible Larmor Frequencies (8.4 through 128 MHz)
Magnetic Field Limit	10,000 Gauss (1 Tesla magnetic field line) - Minimal ferrous material used inside Pump (< 15 grams); non-magnetic ultrasonic motor used inside Pump

PRODUCT STANDARDS REQUIREMENTS	
STANDARDS COMPLIANCE: IEC 60601-1	Yes
STANDARDS COMPLIANCE: IEC 60601-1-2	Yes
STANDARDS COMPLIANCE: IEC 60601-2-24	Yes
STANDARDS COMPLIANCE: AAMI ID26	Yes
STANDARDS COMPLIANCE: UL 60601	Yes
STANDARDS COMPLIANCE: ISO 9919	Yes

REMOTE COMMUNICATIONS	
FCC Certification	Part 15.247, no license required
ETS (European) Certification	brETS 300.328, no license required
Rated RF Output Power	+18 dBm (default), 24 dBm (maximum) Service Selectable.
Frequency Range	2431.3 to 2474.5 MHz (Iradimed Default) Avoids 802.11 bands 1 and 2 France: 2400 to 2450 MHz with Radio programming selection. Service Selectable.
Number of Channels	85 U.S. Channels. Note: A limited frequency mode is available for France. Service Selectable.

3861 SIDECAR™ DUAL PUMP DRIVE	
MECHANICAL CHARACTERISTICS	
Dimensions D x W x H	5.5 x 4.5 x 9.5 Inches (14.0 x 11.4 x 24.1 cm)
Total Weight	6 LBS (2.7 Kg)
Operating Temperature Range	+5^{O} to +40^{O} C
Storage Temperature Range	-40^{O} TO +70^{O} C
Operating Relative Humidity Range	0% to 80% RH, non-condensing
Storage Relative Humidity Range	0% to 95% RH, non-condensing
Pole Clamp Mounting (Pole Diameter) Range	None - Attaches directly to 3860/3860+ pump
ELECTRICAL CHARACTERISTICS	
Power Requirements	18 VDC (derived from MRidium Pump)
Power Consumption	< 19 Volt-Amperes @ 120 VAC nominal
Chassis Leakage Current	< 300 µA RMS (included with MRidium Pump)
Chassis Ground Impedance to Earth	< 0.1 ohms
PERFORMANCE CHARACTERISTICS	
Secondary Pump Performance	
Flow Rate Range - 0 to 100 mL/hr	0.1 to 99.9 mL/hr in 0.1 mL/hr increments
Flow Rate Range - > 100 mL/hr	100 to 1400 mL/hr in 1 mL/hr increments
Flow Rate Display Range	0.1 to 99.9, 100 to 1400 mL/hr
Flow Rate Accuracy	within 5% (for 0.1 to 0.9 mL/Hr, within 10%)
Primary Volume To Be Infused (VTBI) Range	0.1 to 99.9, 100 to 999 mL
Secondary Volume To Be Infused (VTBI) Range	0.1 to 99.9, 100 to 999 mL
Total Volume Infused (VI) Range	0.1 to 99.9, 100 to 9999 mL
Keep Vein Open (KVO) Rate Range	adjustable, 1 to 5 mL/hr, or set rate, whichever is lower.
Keep Vein Open (KVO) Default Rate	1 mL/hr
Patient Line (downstream) Back-Pressure Range	+300 to -100 mmHg
Downstream (proximal) Occlusion Detection Range	1 to 10 PSI (6.9 to 68.8 kPa), user-adjustable
Occlusion Detection Mechanism	Two separate (upstream & downstream) semiconductor force sensors
Occlusion Pressure Measurement Range	1 to 10 PSI (6.9 to 68.8 kPa), with 0.2 PSI resolution
Occlusion Pressure Measurement Accuracy	< 2 PSI (13.8 kPa), or within 10% of setting, whichever is greater.
Occlusion Detection (no flow) Time	typically <30 sec, dependent on selected Flow Rate, 55 min max. @ 1 mL/Hr
Occluded I.V. Line bolus volume (25 mL/Hr to 10 PSI occlusion)	0.7 mL max.
Air-in-Line Detection Method	Ultrasonic bubble detector

Air-in-Line Detector Threshold(s)	> 100 uL
Liquid Source height limits	+100 to -50 cm relative to pump center
Calibration units of measure	mL/hr, mL, Volts, & PSIG
MRI PERFORMANCE	
MRI Magnet Compatibility	Same as Pump (0.2 to 3.0 Tesla MRI Systems)
MRI Larmor Frequency Interference	Same as Pump (No interference at compatible Larmor Frequencies - 8.4 through 128 MHz)
Magnetic Field Limit	Same as Pump (10,000 Gauss (1 Tesla magnetic field line) - Minimal ferrous material used inside unit; non-magnetic ultrasonic motor used inside SideCar Unit)
3865 REMOTE DISPLAY / CONTROL UNIT	
MECHANICAL CHARACTERISTICS	
Dimensions D x W x H	8 x 6 x 10 Inches (20.3 x 15.25 x 25.4 cm)
Total Weight	3.5 LBS (1.6 Kg); 5 LBS (2Kg) with Battery.
Operating Temperature Range	$+5^{O}$ to $+40^{O}$ C
Storage Temperature Range	-40^{O} TO $+70^{O}$ C
Operating Relative Humidity Range	0% to 80% RH, non-condensing
Storage Relative Humidity Range	0% to 95% RH, non-condensing
ELECTRICAL CHARACTERISTICS	
HI/LO Line Voltage Requirements	100 to 240 VAC +/-10%, 50/60 Hz
Power Consumption	< 19 Volt-Amperes @ 120 VAC nominal (<100 VA maximum during 1133 Battery Pack charging)
Spare Battery Charging Bay	For 1133 Rechargeable Lithium Polymer Pack (14.8 v at 6.0 Ah)
Spare Battery Charge Time	< 9 hours to 95% capacity
Chassis Leakage Current	< 100 uA RMS; < 300 µA RMS (Single Fault)
Chassis Ground Impedance to Earth	< 0.1 ohms
MRI PERFORMANCE	
MRI Magnet Compatibility	None specified - 3865 Remote Unit is NOT intended for use inside the Magnet Room

Dose Rate Calculator Factory Default Values
Table 1

Drug Name	Label	Factory Defaults		
		DRC Default Values		
		Primary	Secondary*	Bolus*
Drug?	Dose	0.0 mcg/kg/min	Same as Primary	0.0 mcg/kg/min
	Conc	1.00 mg/ 1 ml	Same as Primary	1.00 mg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	None	None	None
	VTBI	0.0 mL	Same as Primary	0.0 mL
Adenosine	Dose	0.0 mcg/kg	Same as Primary	0.0 mcg/kg
	Conc	3.00 mg/ 1 ml	Same as Primary	3.00 mg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	6 minutes	Same as Primary	1 minute
	VTBI	0.0 mL	Same as Primary	0.0 mL
Dobutamine	Dose	0.0 mcg/kg/min	Same as Primary	0.0 mcg/kg/min
	Conc	1.00 mg/ 1 ml	Same as Primary	1.00 mg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	None	None	None
	VTBI	0.0 mL	Same as Primary	0.0 mL
Propofol	Dose	0.0 mcg/kg/min	Same as Primary	0.0 mg/kg
	Conc	10.0 mg/ 1 ml	Same as Primary	10.0 mg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	None	None	1 minute
	VTBI	0.0 mL	Same as Primary	0.0 mL
Dexmedetomidine	Dose	0.0 mcg/kg/hr	Same as Primary	0.0 mcg/kg
	Conc	4.00 mcg/ 1 ml	Same as Primary	4.00 mcg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	None	None	10 minutes
	VTBI	0.0 mL	Same as Primary	0.0 mL

Note: The values of "UND" in this table denotes an "UNDer-range" value.

Warning: The Factory Default values are provided for initial setup only. Numbers other than zero (0) are used in the table to avoid division by zero (0). Verify all selections prior to beginning the infusion.

***Note:** The secondary infusion feature is not available when starting an infusion with the Dose Rate Calculator with pump software version 3.0.xxxx or higher. Additionally the Bolus dose factory default is "0 mL" with a time of "1 minute" with pump software version 3.2.9 and higher.

Dose Rate Calculator Custom Protocol Values Worksheet
Table 2

Custom Protocol(s)					
Set 1st	Drug Name	Label	DRC User Selected Custom Values		
			Primary	Secondary	Bolus
	Custom:	Dose		Same as Primary	
		Conc		Same as Primary	
	Name:	Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	
	Adenosine	Dose		Same as Primary	
		Conc		Same as Primary	
		Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	
	Dobutamine	Dose		Same as Primary	
		Conc		Same as Primary	
		Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	
	Propofol	Dose		Same as Primary	
		Conc		Same as Primary	
		Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	
	Dexmedetomidine	Dose		Same as Primary	
		Conc		Same as Primary	
		Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	

MRidium Infusion Pump Serial Number:_____

Note: Retain a copy of this Worksheet with Service Records for future use and/or changes.

Note: The Custom Drug Protocol values are those programmed by the user in the Service Mode. If no values are programmed by the user, the Factory Default values are used in the Dose Rate Calculator.

Important: The First Custom Drug Protocol selected and saved after clearing the Custom Drug Settings will be set as the new default drug when the Dose Rate Calculator is first selected in the Normal Use mode. It will also be the only drug choice, if the drug Table is turned off after the Custom Drug have been set by the user.

Warning: The Factory Default values are provided for initial setup only. Numbers other than zero (0) are used in the table to avoid division by zero (0). Verify all selections prior to beginning the infusion.

STANDARD USER SETTING RANGES AND DEFAULTS

Characteristic	Specification Range	Initial Start-Up (Factory Default) Value
Primary Flow Rate Range - 0 to 100 mL/hr	0.1 to 99.9 mL/hr in 0.1 mL/hr increments	1 mL/hr
Primary Flow Rate Range - > 100 mL/hr	100 to 1400 mL/hr in 1 mL/hr increments	1 mL/hr
Secondary Flow Rate Range - 0 to 100 mL/hr	0.1 to 99.9 mL/hr in 0.1 mL/hr increments, 100 to 1400 mL/hr in 1mL increments.	0.1 mL/hr
Primary Volume To Be Infused (VTBI) Range	0.1 to 999 mL	0 mL
Secondary Volume To Be Infused (VTBI) Range	0.1 to 999 mL	0 mL
Total Volume Infused (VI) Range	0.1 to 9999 mL	0 mL
Keep Vein Open (KVO) Rate Range	adjustable, 0 to 5 mL/hr, in 1 mL/hr increments; 0 denotes KVO is off.	1 mL/hr
Bolus Rate Range	0.1 to 99.9, 100 TO 1400 mL/hr in 1 mL/hr increments	500 mL/hr
Bolus To Be Infused Range	0.1 to 999 mL Upper limit determined by primary VTBI	0 mL
Occlusion Pressure Limit Range	1 to 10 PSI	None, always retains last setting.
Dose Programming - Patient Weight Range	0.1 to 160 Kg in 0.1 Kg increments	0.0 Kg
Dose Programming - Drug Concentration Range	0.1 to 99.9 mg/mL	Varies, dependent on selected Drug.
Dose Programming CONC - Diluent Range	1 to 999 mL	1 mL
Dose Programming - Dose in mg/Kg/min Range	0.1 to 9999 mg	0.0 mg; 0 mL (Software Version 3.2.9 and higher)
Dose Programming - Volume to Be Infused	0.1 to 999 mL	0 mL
Dose Programming - Time Range	1 to 99 min; 0.1 to 99.9 min (Software version 3.0.xxxx and higher)	Varies, dependent on selected Drug; 1 min. (Software Version 3.2.9 and higher)
Alarm Sound Volume	> 65 dBA at 1 meter, Settings = Minimum to Maximum (Graphical Display)	None, always retains last setting.
Drug Library Option	Allows selection of 1 of 5 drugs used in Dose Rate Calculator. When OFF, only one drug (Drug?) is available.	Default value is on. (Drug Library choices are available)

Note: Refer to Section 7 for MRI-SpO2 Specifications and factory default settings. Refer to Table 3 for additional settings and ranges available for DERS infusions.

Additional Dose Rate Calculator Settings and Ranges
(for use with Dose Rate Calculator and Dose Error Reduction System (DERS))
Table 3

Units Value	Minimum	Default	Maximum	Notes
Dose				
mcg/kg/min	0.01	0	9,999	(a)
mg/kg/min	0.01	0	9,999	(a)
mcg/kg/hr	0.01	0	9,999	(a)
mg/kg/hr	0.01	0	9,999	(a)
mcg/kg	0.01	0	9,999	(a)
mg/kg	0.01	0	9,999	(a)
mcg/min	0.01	0	9,999	(a)
mg/min	0.01	0	9,999	(a)
mcg/hr	0.01	0	9,999	(a)
mg/hr	0.01	0	9,999	(a)
mg	0.01	0	9,999	(b)
mcg	0.01	0	9,999	(b)
mL	0.1	0	999.9	(c)
mU/kg/min	1	0	99,999	(b) (d)
Units/kg/hr	1	0	99,999	(b) (d)
mU/kg/hr	1	0	99,999	(b) (d)
Units/min	1	0	99,999	(b) (d)
Units/hr	1	0	99,999	(b) (d)
mU/hr	1	0	99,999	(b) (d)
mU/min	1	0	99,999	(b) (d)
Units	1	0	99,999	(b) (d)
mU	1	0	99,999	(b) (d)
Units/kg	1	0	99,999	(b) (d)
mU/kg	1	0	99,999	(b) (d)

Units Value	Minimum	Default*	Maximum	Notes
Concentration				
mg	0.01	1	9,999	(a)
mcg	0.01	None	9,999	(a)
Units	1	1	25,000	(b)
mU	1	None	25,000	(b)
mL	1	1	999	(a)

IMPORTANT: When using DERS, the actual use range will vary dependent on hospital-set limits. Consult Facility Drug Library control personnel for specifc details.

* With the Factory Default drug library, the Concentration default numeric values will match those found in Table 1 in Appendix A for these 5 drug types.

NOTES:

(a) Standard Drug Library choices for the 5 default drug types (non-DERS).

(b) With Software version 3.0.xxxx and higher, the expanded Drug Library choices for the 5 drug types and DERS Drug Library.

(c) With Software version 3.2.9 and higher, the "mL" selection is available as a Dose unit choice. Additionally, the Bolus Dose Factory Default is "0 mL" with a Time of "1 Minute" for the 5 default drug types (non-DERS).

(d) With Software version 3.2.9 and higher, when selecting the units-based Dose Units values, the Concentration Units Value must first to set to either "units", or "mU".

Infusion Set Specifications

I.V. ADMINISTRATION SETS	
General Specifications	
IV Set Materials used	PVC Tubing (No Latex or DEHP)
Integral Free Flow Protection	Custom flow preventer incorporated into each set. Fluid free-flow can't occur without mechanically opening the flow preventer.
Air-Trapping Feature	Air-Trapping "Y" sites used
Access Device Connection	Male Luer Lock fitting provided for connection to Access Port
Access Device Connection - needleless port	Yes
IV Set Injection Site Sealing	All sets include self-sealing injection sites
IV Set Maximum Pressure Withstand	> 14 PSI
IV Set Maximum Pull Force Withstand	> 15 Nt (3.3 lbs.), per ISO 8536-4
IV Set Operating Temperature Range	$+5^{o}$ to $+40^{o}$ C
IV Set Storage Temperature Range	-40^{o} to $+52^{o}$ C
IV Set Storage Shelf Life	4 years
IV Set Infusion-Use Life	6 hours
Recommended Fluid Container Height above Pump	0 to 60 cm (0 to 23.6 inches)
1055 Bypass Set	
Primary Set Length	85 inch (215 cm)
Set Inner Diameter	0.108 inch (2.7 mm)
Set Outer Diameter	0.152 inch (3.9 mm)
Priming Volume	12 mL max
1056 Standard Set	
Primary Set Length	118 inch (300 cm)
Set Inner Diameter	0.108 inch (2.7 mm)
Set Outer Diameter	0.152 inch (3.9 mm)
Priming Volume	18 mL max
1057 Syringe Set	
Primary Set Length	85 inch (215 cm)
Set Inner Diameter	0.050 inch (1.3 mm)
Set Outer Diameter	0.092 inch (2.3 mm)
Priming Volume	4 mL max
1058 Extension Set	
Primary Set Length	72 inch (185 cm)
Set Inner Diameter	0.108 inch (2.7 mm)
Set Outer Diameter	0.152 inch (3.9 mm)
Priming Volume	10 mL max

APPENDIX B
REPAIR

All repairs on products under warranty must be performed by Iradimed Corporation personnel, or an authorized Iradimed Corporation Service and Repair Center. Unauthorized repairs will void the warranty.

If a pump fails to function properly or requires maintenance, contact Iradimed Corporation Technical Service at 1-407-677-8022 within the U.S., +001-407-677-8022 from outside the U.S.(during normal business hours EST), or by E-mail at techsupport@iradimed.com. Iradimed Corporation Technical Service will advise you of the corrective action required. If you are advised to return the pump to Iradimed Corporation for repair, please do the following:

a. Obtain a Return Authorization Number. This will ensure proper routing and facilitate timely repair of your pump.

b. Clean Pump prior to shipment. Do not ship contaminated product to IRadimed Corporation for repair.

c. Package the pump with adequate protection. If available, use the original carton and packing materials in which the pump was shipped from Iradimed Corporation.

d. Include a brief description of the problem as well as the name, address and phone number of the person to be contacted for additional information.

e. Include a purchase order with the pump being returned if it is out of warranty; Iradimed Corporation Technical Services can advise you of your pump's warranty status if need be. Repairs will be made at Iradimed Corporation's current list price for the replacement part(s) plus a reasonable labor charge.

f. Ship the pump transportation prepaid, to the location specified by your Iradimed Corporation Service Representative with the Return Authorization Number written on the outside of the shipping carton. Repairs will be made, normally, within two (2) weeks and the pump will be returned to you prepaid.

To ensure full reliability, it is recommended that all repairs be made by an Iradimed Corporation Authorized Service and Repair center. For repair at your facility, a competent individual experienced in the repair of pumps can repair the pump only IF it is authorized by Iradimed Corporation Technical Service prior to the repair.

CAUTION: No repair should ever be attempted by anyone not having a complete knowledge of the repair of Iradimed Corporation pumps. Only replace damaged parts with components manufactured or sold by Iradimed Corporation. Contact the Iradimed Corporation Technical Service and Repair Center for service and technical assistance.

APPENDIX C
WARRANTY INFORMATION

Iradimed Corporation warrants its major products (i.e. pumps, remote displays, secondary pumps) to be free from defects in materials and workmanship for a period of twelve (12) months from the date of original delivery to the buyer or to buyer's order, provided that same is properly operated under conditions of normal use, and that periodic maintenance and service is performed. A ninety (90) day warranty applies to limited-life parts (e.g.1133 MRI Compatible Battery Pack, 1170 Fiberoptic SpO2 sensor, and Series 1000 infusion sets). A thirty (30) day warranty applies to all parts and accessories not listed above.

This warranty will become null and void if product has been repaired other than by Iradimed Corporation, or its authorized representative, or if the product has been subject to misuse, accident, negligence, or abuse.

Iradimed Corporation's sole obligation under this warranty is limited to repairing a product which has been reported to Iradimed Corporation's Technical Service Center during normal business hours and shipped transportation prepaid. Iradimed Corporation is not liable for any damages including, but not limited to, incidental damages, consequential damages or special damages.

This warranty is in lieu of any other warranties, guarantees or conditions, including

merchantability or fitness for a particular purpose. The remedies under this warranty are exclusive and Iradimed Corporation neither assumes nor authorizes anyone to assume for it any other obligation in connection with the sale or repair of its products.

A purchased Maintenance Extension agreement provides for an additional 1, 2, or 3 years of authorized repair for major products. The maintenance extension period will begin at the end of the standard warranty period, and continue until the end of the maintenance extension period purchased. The extended maintenance does not apply to equipment which has been subject to abuse or neglect.

Maintenance Extensions purchased after the standard warranty has expired shall require a physical inspection by Iradimed Corporation prior to purchase of any Maintenance Extension. An additional service fee may also be required to bring the out of warranty product(s) within specifications before any maintenance extension can be activated. (Cost of such inspection and possible repair to the product will be communicated to customer at that time). We reserve the right to refuse the sale of Maintenance Extension to any Product.

Iradimed Corporation warrants any such product subject to a Maintenance Extension agreement shall, other than its expendable parts, provided that same is properly operated under conditions of normal use, and that periodic maintenance and service is performed; be repaired by Iradimed and restored to full operational specification as where applicable at the time of original manufacture. Any Maintenance Extension will become null and void if product has been repaired other than by Iradimed Corporation, or its authorized representative, or if the product has been subject to misuse, accident, negligence or abuse.

Should a unit perform outside of Iradimed specifications and cannot be corrected by on site technicians with instruction and support from Iradimed and unit must be returned to Iradimed for repair, a loaner unit, if available, may be provided.

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APPENDIX D
MANUFACTURERS TECHNICAL DECLARATION

EMC Information Tables as required by EN 60601-1-2:2000 Clause 6

In accordance with EN 60601-1-2:2000 Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic Compatibility – Requirements and tests

1. "Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents" (the following tables).
2. "Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment".
3. "The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it is used".

The following tables (as required in EN 60601-1-2:2000) provide information regarding the Electromagnetic Compatibility (EMC) of this product and its accessories.

Table 201—Guidance and manufacturer's declaration— electromagnetic emissions—for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration—electromagnetic emissions		
The MRidium 3860 System is intended for use in the electromagnetic environment specified below. The customer or the user of the MRidium 3860 System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The MRidium 3860 System must emit electromagnetic energy in order to perform its intended function (remote communications within an specific band for WLAN; i.e. 2.431 to 2.474 GHz). Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The MRidium 3860 System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 202—Guidance and manufacturer's declaration— electromagnetic immunity—for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration—electromagnetic immunity			
The MRidium 3860 System is intended for use in the electromagnetic environment customer or the user of the MRidium 3860 System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT(>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT(>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MRidium 3860 System requires continued operation during power continued operation during power mains interruptions, it is recommended that the MRidium 3850 System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE—UT is the a.c. mains voltage prior to application of the test level.

Table 203—Guidance and manufacturer's declaration— electromagnetic immunity—for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration—electromagnetic immunity			
The MRidium 3860 System is intended for use in the electromagnetic environment customer or the user of the MRidium 3860 System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MRidium 3850 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 V	$d = 1.17 \sqrt{P}$
	10 Vrms 150 kHz to 80 MHz outside ISM bands[a]	10 V	$d = 1.20 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 Vrms 80 MHz to 2.5 GHz	10 V/m	$d = 1.20 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,c should be less than the compliance level in each frequency range.d Interference may occur in the vicinity of equipment marked with the following symbol: IEC 60417, No. 417-IEC5140, "Source of Non-Ionizing Radiation" Symbol

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MRidium 3850 System is used exceeds the applicable RF compliance level above, the MRidium 3850 System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MRidium 3850 System.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m

Table 205—Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM—for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the MRidium 3860 System				
The MRidium 3860 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MRidium 3860 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MRidium 3860 System as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d = 1.17 \sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.77
1	1.17	1.2	1.17	2.33
10	3.8	3.8	3.8	7.67
100	11.67	12	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.				
NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.				
NOTE 2—The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.				
NOTE 3—An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.				
NOTE 4—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.				

DECLARATION OF CONFORMITY

Application of Council Directive(s) R&TTE Directive 1999/5/EC

Regulation(s) to which Conformity is Declared R&TTE Directive 1999/5/EC

Standard(s) to which Conformity is Declared EN 300 328, IEC 60601-1, IEC 60601-1-2

Manufacturer's Name Iradimed Corporation

Manufacturer's Address 7457 Aloma Ave., Winter Park, FL 32792 USA

Importer's Name Refer to accompanying Packing Slip

Importer's Address Refer to accompanying Packing Slip

Type of Equipment MRIdium 3860 Infusion Pump System and accessories

Model No(s). 3860 Series and 3865 Series

Serial No(s). Refer to accompanying Packing Slip

Year of Manufacture Refer to accompanying Packing Slip

Certification Method(s) Self-certified

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s), Regulation(s) and/or Standard(s).

Place Winter Park, FL

Date July 16, 2009

Francis Casey
(Signature)

Francis Casey
(Full Name)

Regulatory Affairs
(Position)

Declaration of Conformity with Regard to the EU Directive 1999/5/EC (R&TTE Directive)

Scope

The information in this document is applicable to the MRidium 3860 System using the 3860 MRI Infusion Pump with 2.4 GHz FHSS Transciever, and 3865 Remote Display Controller with the 2.4 GHz FHSS Tranciever, and othe related products as they come to market.

The equipment operates in the bands (or portions of) 2400 to 2483.5 MHz. National regulations may require that operations be limited to a portion of the frequency ranges identified above. See the National Restrictions section for full details.

Declaration of Conformity

Czech (CS) Česky	Toto zařízení je v souladu se základními požadavky a ostatními odpovídajícími ustanoveními směrnice 1999/5/ES
Danish (DA) Dansk	Dette udstyr er i overensstemmelse med de væsentlige krav og andre relevante bestemmelser i Direktiv 1999/5/EF.
Dutch (NL) Nederlands	Dit apparaat voldoet aan de essentiele eisen en andere van toepassing zijnde bepalingen van de Richtlijn 1999/5/EG
Estonian (ET) Eesti	See seade vastab direktiivi 1999/5/EÜ olulistele nõuetele ja teistele asjakohastele sätetele.
English (EN)	This equipment is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.
German (DE) Deutsch	Dieses Gerät entspricht den grundlegenden Anforderungen und den weiteren entsprechenden Vorgaben der Richtlinie 1999/5/EG
Greek (EL) Ελληνική	Αυτός ο εξοπλισμός είναι σε συμμόρφωση με τις ουσιώδεις απαιτήσεις και άλλες σχετικές διατάξεις της Οδηγίας 1999/5/ΕΚ
Finnish (FI) Suomi	Tämä laite täyttää direktiivin 1999/5/EY olennaiset vaatimukset ja on siinä asetettujen muiden laitetta koskevien määräysten mukainen.
French (FR) Français	Cet appareil est conforme aux exigencies essentielles et aux autres dispositions pertinentes de la Directive 1999/5/CE
Hungarian (HU) Margyar	Ez a készülék teljesíti az alapvető követelményeket és más 1999/5/EK irányelvben meghatározott vonatkozó rendelkezéseket.
Icelandic (IS) Íslenska	Þetta tæki er samkvæmt grunnkröfum og öðrum viðeigandi ákvæðum Tilskipunar 1999/5/EB
Italian (IT) Italiano	Questo apparato è conforme ai requisiti essenziali ed agli altri principi sanciti dalla Direttiva 1999/5/CE
Latvian (LV) Latviski	Šī iekārta atbilst Direktīvas 1999/5/EK būtiskajām prasībām un citiem ar to saistītajiem noteikumiem.
Lithuanian (LT) Lietuvių	Šis įrenginys tenkina 1999/5/EB Direktyvos esminius reikalavimus ir kitas šios direktyvos nuostatas.

Maltese (MT) Malti	Dan l-apparat huwa konformi mal-htigiet essenzjali u l-provedimenti l-ohra rilevanti tad- Direttiva 1999/5/KE
Norwegian (NO) Norsk	Dette utstyret er i samsvar med de grunnleggende krav og andre relevante bestemmelser i EU-direktiv.1999/5/EC
Polish (PL) Polski	Urządzenie jest zgodne z ogólnymi wymaganiami oraz szczególnymi warunkami określonymi Dyrektywą UE: 1999/5/WE
Portuguese (PT) Português	Este equipamento está em conformidade com os requisitos essenciais e outras provisos relevantes da Directiva 1999/5/CE

Applicable Standards

The following standards were applied during the assessment of the product against the requirements of the Directive 1999/5/EC:

- Radio: EN 300 328
- EMC: EN 60601-1-2
- Safety: EN 60601-1-1 and EN 60601-2-24

CE Marking

For the 2.4 GHz wireless products such as the MRidium 3860 MRI Infusion Pump with 2.4 GHz FHSS Transciever, and the 3865 Remote Display Controller with the 2.4 GHz FHSS Tranciever, the following CE mark and class-2 identifier are added to the equipment.

CE ⓘ

National Restrictions

In the majority of the EU and other European countries, the 2.4 GHz band has been made available for the use of ISM (Industrial, Scientific, and Medical) communication. Table 1 provides an overview of the regulatory requirements in general that are applicable for the 2.4 GHz band.

Later in this section you will find an overview of countries in which additional restrictions or requirements or both are applicable.

The requirements for any country may evolve. Iradimed Corporation recommends that you check with local authorities for the latest status of their national regulations for 2.4 GHz ISM (Industrial, Scientific, and Medical) communication.

Frequency Band: 2400 - 2483.5 MHz

Max Power Level (EIRP): 100 mW

Indoor and Outdoor Use: Yes

The following sections identify countries having additional requirements or restrictions than those listed above:

France

For 2.4 GHz, the output power is restricted to 10 mW EIRP when the product is used outdoors in the band 2454 - 2483.5 MHz. There are no restrictions when used in other parts of the 2.4 GHz band. For use in France, channel selection is limited to 2400 to 2450 MHz. Check http://www.arcep.fr/ for more details.

Italy

This product meets the National Radio Interference specifications and the requirements in the National Frequency Allocation Table for Italy. Operating wireless equipment requires a "general authorization" unless it is operated within the boundaries of the owner's property. Please check with http://comumicazioni.it/it for more information.

Questo prodotto è conforme alla specifiche di Interfaccia Radio Nazionali e rispetta il Piano Nazionale di ripartizione delle frequenze in Italia. Se non viene installato all'interno del proprio fondo, l'utilizzo di prodotti Wireless LAN richiede una "Autorizzazione Generale". Consultare http://www.comunicazioni.it/it per maggiori dettagli.

Latvia

Any outdoor usage of the 2.4 GHz band requires an authorization form the Electronic Communications Office. Please check http://www.esd.lv for more information.

Antennas

The 2.4 GHz wireless ISM (Industrial, Scientific, and Medical) communication products described in this document have dedicated antennas which should not be removed or replaced with any antenna that is not supplied directly from Iradimed Corporation or its representatives.

Operating Frequency

The operating frequency is pre-set at the factory during manufacturing. Manual setting of the operating frequency can only be done by qualified service personnel with a service

password. Instructions are provided in the Service documentation regarding the appropriate choices and settings for specific geographic areas. It is important that the operating frequency is correctly configured to meet the local regulations.

Changing Output Power

The output power is pre-set to 63 mW at the factory during manufacturing. Manual setting of the output power above 100 mW can only be done by qualified service personnel with a service password. The only available ouput power choices are Level 1 (10 mW), Level 2 (63 mW – factory default), or Level 3 (250 mW). Instructions are provided in the Service documentation regarding the appropriate choices and settings for specific geographic areas. It is important that the output power is correctly configured to meet the local regulations.

Note If you still have questions regarding the compliance of these products, or you cannot find the information you are looking for on the Iradimed Corporation website, http://iradimed.com, please send an email request to Iradimed Corporation at:

techsupport@iradimed.com

APPENDIX E
ACCESSORIES

Infusion Sets:

1055-50 Bypass Infusion Set (carton of 50)

1056-50 Infusion Set (carton of 50)

1057-50 Syringe Adapter Set (carton of 50)

1058-50 Extension Set (carton of 50)

Accessories:

1119 - MRidium™ MRI IV Pole (Non-Magnetic (non-ferrous) I.V. Pole, 1.25 in. [3.2 cm] dia.

1120 - 3860 Pump MRI Power Supply

1121 - AC Power Adapter Power Cord, 3 ft. [1M] (length), medical grade

1125 - MRidium Service Manual CD

1122 - AC Adapter/To Pump Interconnect Cable, 10 ft. [3.05 M] (length)

1138 - 3860/3860+ Operators Manual

1128 - AC Power Cord, 10 ft. [3.05 M] (length), medical grade

1133 - MRI-Compatible Battery Pack

1145 - DERS Software Update Kit

1170 - Fiberoptic SpO_2 Sensor Kit

1171 - Fiberoptic SpO_2 Sensor Grip Kit (Sensor Grips Only)

3861 - Channel B Pump Drive Assembly (Side-mount)

3865 - Remote Display/Battery Charger

LB2025 - Channel ID Marker Sheet

AM04 - MRidium™ 3860/3860+ Pump System Software Update Card

Note: The 3860+ designates a 3860 Pump with the Extended Flow Rate Range and Masimo SpO_2 Monitoring.

WARNING: Use only listed accessories with the MRidium™ 3860/3860+ MR Pump/Monitor.

APPENDIX F

TROUBLESHOOTING

Problem	Possible Cause	Solution
Pump won't turn on.	Unit not turned on.	Turn on unit by pressing 1 (On) control key.
	No AC power/battery depleted.	Plug power cord into pump and AC power source or replace battery pack with charged battery.
	Blown fuse(s).	Refer to qualified service personnel.
	AC power source has low voltage.	Switch AC power cord to power receptacle with sufficient voltage.
No Fluid Flow.	Administration Set is not connected to fluid source.	Attach Administration Set to fluid source.
	Set is not mounted in pump.	Open pump door and re-load Administration Set.
	Administration Set does not mount onto pump.	Select appropriate MRidium™ 1000 Series Administration Set for pump.
	Patient line is kinked.	Straighten kinked line. Inspect for damage or leaks, and replace if necessary.
	Roller Clamp is closed.	Open Roller or slide clamp.
	Damaged Set or line is leaking.	Replace damaged Administration Set.
Pump won't start.	Door Open.	Reseat door, close completely.
	Set is not properly mounted in pump.	Open pump door and re-load Administration Set.
	Pump program has not been entered.	Enter Pump settings and initiate Pump by pressing START/STOP for appropriate channel.

Problem	Possible Cause	Solution
Fluid Leaking from Administration Set.	Fluid side of Set is not properly connected.	Inspect for damage or leaks, and replace if necessary.
	Damaged Set is leaking.	Examine Set to locate leak. Disconnect Set from the patient. Replace and resume infusion.
Unit won't operate on battery.	Battery not properly charged.	Plug pump power cord into AC power source until battery is fully charged.
	Aged battery won't hold charge.	Plug pump power cord into AC power source until battery is fully charged. If battery won't charge, replace battery pack.
Battery operation is too short.	Battery not properly charged.	Plug pump power cord into AC power source until battery is fully charged.
	Aged battery won't hold charge.	Plug pump power cord into AC power source until battery is fully charged. If battery won't charge, replace battery pack and charge again. If problem persists, refer to qualified service personnel.
Battery is hard to remove from Pump.	Battery cell failure due to over discharge or individual cell failure.	Remove/replace battery in pump, using appropriate tools as needed. Refer damaged battery to qualified service personnel.
No audible alarm heard.	Occlusion Pressure limits not set properly.	Adjust limits to clinically appropriate level.
	Alarm volume set too low for the use environment.	Adjust alarm volume for the intended use environment.
	Faulty alarm speaker.	Refer to qualified service personnel.
Continuous audible alarm heard.	Faulty pump hardware.	Refer to qualified service personnel.
Fluid delivery seems inaccurate.	Pump not calibrated.	Refer to qualified service personnel.
Keys won't function.	Key not pressed firmly.	Repeat key press pushing in firmly.
	Faulty key panel.	Refer to qualified service personnel.

Problem	Possible Cause	Solution
Pump settings are restored to default.	Pump turned off for longer than one (1) hour between uses.	Train appropriate personnel that turning off the pump for more than one (1) hour resets pump settings.
	Pump settings changed accidentally.	Double check key sequence for feature chosen for correct key sequence. Was “New Patient” chosen?
	History Checksum Error, internal battery problem.	Refer to qualified service personnel.
History Log data are lost accidentally.	Pump memory is damaged or internal backup battery is low.	Refer to qualified service personnel. Memory can only be reset by manufacturer.
Infusion prematurely stopped.	Occlusion overpressure, inlet occlusion or patient occlusion.	Examine Set to locate occlusion. Disconnect Set from the patient to clear occlusion. Re-prime line and resume infusion.
	Bubble Detected alarm occurred.	Examine Set to locate air bubble. Disconnect Set from the patient. Purge Air in Line. Re-prime line and resume infusion.
	Faulty pump hardware.	Refer to qualified service personnel.
Unit alarms after each infusion start.	Occlusion pressure alarm limit is set too low.	Examine patient infusion site for source of occlusion or infiltration. Re-adjust alarm limits as described in **Paragraph 4.7.4**
	Bubble Detected alarm occurred.	Examine Set to locate air bubble. Disconnect Set from the patient. Purge Air in Line. Re-prime line and resume infusion.
Pump clock is not correct.	Clock not properly adjusted to local time after receipt.	Adjust clock time as described in service manual.
	Clock battery has become depleted.	Refer to qualified service personnel.
	Summer/Winter time change.	Adjust clock as described in service manual.

Problem	Possible Cause	Solution
Infusion stops.	Air is present in the Administration Set.	Examine Set to locate air bubble. Disconnect Set from the patient. Purge Air in Line. Re-prime line and resume infusion.
	Administration Set Roller clamp is closed.	Open Roller Clamp on Administration Set.
	Administration Set improperly loaded on pump drive.	Open pump door, remove Set and reload Set following instructions.
	Kinked Set causes Occlusion Alarm.	Straighten Set and re-start infusion.
	Patient Access Device is blocked.	Change Patient Access Device.
Inlet Occlusion Alarm occurs when using 1057 Syringe IV Set	1057 IV set air vent is not open, which prevents normal fluid flow.	Open the white cap of the 1057 IV set air vent to allow air flow into the syringe.
	Occlusion Pressure Alarm limit is set too low for the smaller diameter IV tubing.	Select a higher Occlusion Pressure Alarm limit to allow normal flow. Alarm limits may need to be set between 8 and 10 PSI, depending on fluid temperature and viscosity.
Recurring "Check Door" or "Close Door" messages occur when pump door is closed.	The Door Clamp rubber pin is bent or damaged.	The Door Clamp rubber pin needs replacement. Refer to qualified service personnel.

Problem	Possible Cause	Solution
Remote Display will not communicate with selected pump	Pump is not within range.	Reposition pump to establish communication. Verify pump is within 90 ft (30 m) of Remote Display.
	Pump is not operational.	Verify pump power is on and radio antenna is securely attached to both Pump and Remote Display.
	Pump and Remote Display are not set at the same channel.	Verify in the Set Comm Channel menu option that both Pump and Remote Display are set to the same comm channel. If not, change the Remote Display to the Pump's comm channel.
	Local radio interference prevents communication.	Select alternate comm channels for both Pump and Remote Display. However, follow the installation procedure (Remote Display Installation in Section 2) to avoid the possibility of setting 2 Pumps on the same channel.
	MRI Magnet Room shielding reduces radio signal strength to prevent communication.	Refer to qualified service personnel. Radio transmission power can be increased (within limits) by service personnel to accommodate most MRI magnet rooms. Contact Iradimed Corporation for additional information.

APPENDIX G

1119 I.V. POLE ASSEMBLIES AND PARTS DESCRIPTIONS

General Precautions

- Federal law in the USA restricts this device to sale by or on the order of a physician.
- For safe operation, use only Iradimed Corporation recommended MRI-compatible or MRI-safe accessories.
- Always secure the IV Pole wheel locks after positioning within the MRI Magnet Room.
- Product damage may occur unless proper care is exercised during unpacking and installation. Use only recommended assemblies and parts. Any replacement component must be non-magnetic for safe operation.
- Refer all service to Iradimed Corporation, or Authorized Service Representatives.
- A maximum number of two (2) pumps can be safely used on any one (1) IV pole, mounted no more than 54 inches [137cm] from the floor.

NOTE: There are several 1119 I.V. Pole configurations. When using the following assembly instructions, please match the appropriate instructions to your specific 1119 I.V. Pole.

Routine Maintenance

Periodically check all mounting hardware. Tighten as necessary for optimal operation.

Cleaning the Mounting Assembly

1. The mounting assembly may be cleaned with most mild, non-abrasive solutions commonly used in the hospital environment (e.g. diluted bleach, ammonia, or alcohol solutions).

2. The surface finish will be permanently damaged by strong chemicals and solvents such as acetone and trichloroethylene.

3. Do not use steel wool or other abrasive material to clean the mounting assembly.

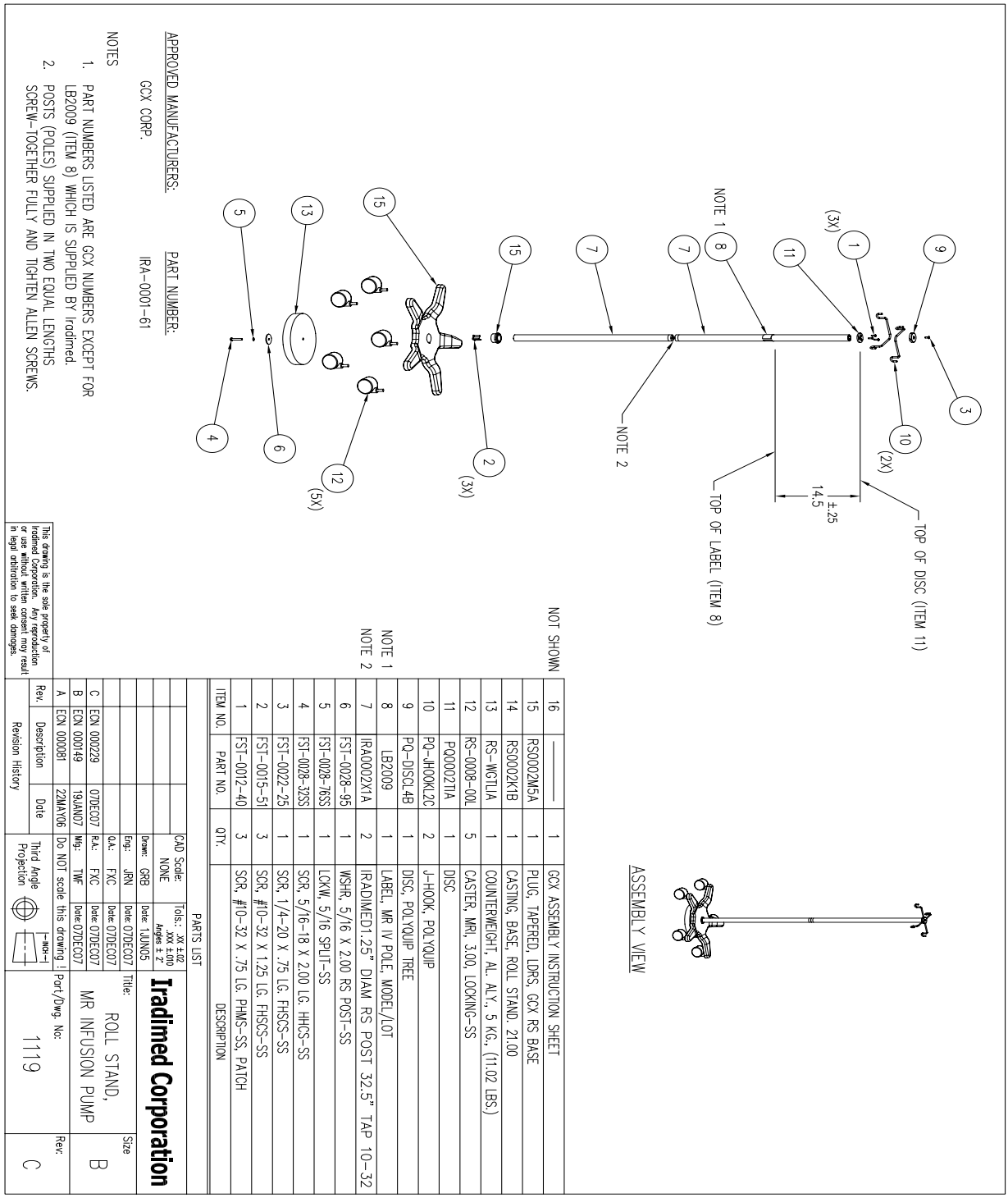
4. Damage caused by the use of unapproved substances or processes will not be covered by warranty. We recommended that you test any cleaning solution on a small area of the mounting assembly that is not visible to verify compatibility.

5. Never submerge the roll stand or allow liquids to enter the mounting assemblies Wipe any cleaning agents off the mounting assembly immediately, using a water-dampened cloth. Dry all mounting assemblies thoroughly after cleaning.

CAUTION: Iradimed Corporation makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection. Consult your hospital's infection control officer or epidemiologist. To clean or sterilize mounted instruments or accessory equipment, refer to the specific instructions delivered with those products.

IV POLE CONFIGURATION 1

1119 I.V. POLE ASSEMBLIES AND PARTS DESCRIPTIONS



NOT SHOWN

ITEM NO.	PART NO.	QTY.	DESCRIPTION
16	————	1	GCX ASSEMBLY INSTRUCTION SHEET
15	RSG002M5A	1	PLUG, TAPERED, LDRS, GCX RS BASE
14	RSG002K1B	1	CASTING, BASE, ROLL STAND, 21.00
13	RS-WGTLIA	1	COUNTERWEIGHT, AL ALY., 5 KG., (11.02 LBS.)
12	RS-0008-00L	5	CASTER, MRI, 3.00, LOCKING-SS
11	PQG00021TA	1	DISC
10	PQ-JHOOKL2C	2	J-HOOK, POLYQUIP
9	PQ-DISCL4B	1	DISC, POLYQUIP TREE
8	LB2009	1	LABEL, MR IV POLE, MODEL/LOT
7	IRA0002X1A	2	IRADIMED1.25" DIAM RS POST 32.5" TAP 10-32
6	FST-0028-95	1	WSHR, 5/16 X 2.00 RS POST-SS
5	FST-0028-76SS	1	LCKW, 5/16 SPLIT-SS
4	FST-0028-32SS	1	SCR, 5/16-18 X 2.00 LG. HHCS-SS
3	FST-0022-25	1	SCR, 1/4-20 X .75 LG. FHSCS-SS
2	FST-0015-51	3	SCR, #10-32 X 1.25 LG. FHSCS-SS
1	FST-0012-40	3	SCR, #10-32 X .75 LG. PHMS-SS, PATCH

PARTS LIST

APPROVED MANUFACTURERS:

GCX CORP.

PART NUMBER:

IRA-0001-61

NOTES

1. PART NUMBERS LISTED ARE GCX NUMBERS EXCEPT FOR LB2009 (ITEM 8) WHICH IS SUPPLIED BY Iradimed.
2. POSTS (POLES) SUPPLIED IN TWO EQUAL LENGTHS SCREW-TOGETHER FULLY AND TIGHTEN ALLEN SCREWS.

Rev.	Description	Date
A	ECN 000081	22MAY06
B	ECN 000149	19JAN07
C	ECN 000229	07DEC07

CAD Scale: NONE
Tols.: .XX ±.02, .XXX ±.010, Angles ± 2°
Drawn: GRB Date: 1JUN05
Eng: JRN Date: 07DEC07
Q.A.: FXC Date: 07DEC07
R.A.: FXC Date: 07DEC07
Mfg: TWF Date: 07DEC07
Third Angle Projection
Do NOT scale this drawing !
INCH

Iradimed Corporation

Title: ROLL STAND, MR INFUSION PUMP

Size: B

Port/Dwg. No: 1119

Rev: C

This drawing is the sole property of Iradimed Corporation. Any reproduction or use without written consent may result in legal arbitration to seek damages.

Installation Guide

Iradimed 1119 MRI Pump Roll Stand Kit

The purpose of this guide is to:

1. Describe assembly of Roll Stand Post and Base (page H-3).
2. Describe attachment of IV Bag Hooks to IV Pole (page H-3).
3. Describe assembly of IV Poles (page H-4).

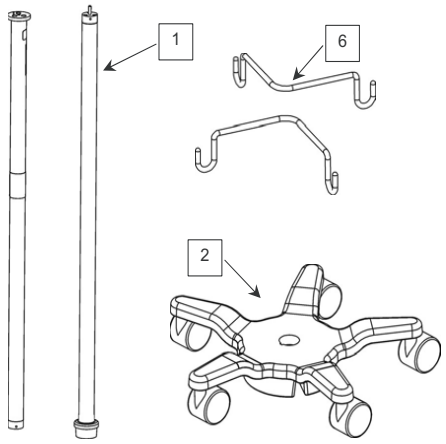
General Precautions

- Federal law in the USA restricts this device to sale by or on the order of a physician.
- For safe operation, use only Iradimed Corporation recommended MRI-compatible or MRI-safe accessories.
- Always secure the IV Pole wheel locks after positioning within the MRI Magnet Room.
- Product damage may occur unless proper care is exercised during unpacking and installation. Use only GCX Corporation recommended assemblies and parts. Any replacement component must be non-magnetic for safe operation.
- Refer all service to Iradimed Corporation, or GCX Corporation Authorized Service Representatives.
- A maximum number of two (2) pumps can be safely used on any one (1) IV pole, mounted no more than 54 inches [137cm] from the floor.

Parts Reference

The following parts and hardware are included in this installation kit (see illustrations for parts; hardware not shown):

Item #	Description	Qty
1	IV Pole, 66" 2-piece	1
2	Base (with 10 lb. Counterweight)	1
3	5/16-18 x 1" Hex Head Cap Screw (HHCS)	1
4	5/16 Flat Washer	1
5	5/16 Split Lock Washer	1
6	Hook, IV Bag	2
7	1/4-20 x 3/4" Flat Head Socket Cap Screw (FHSCS)	1
8	Tree Disc	1
9	5/32" Hex Wrench	1
10	3/32" Hex Wrench	1

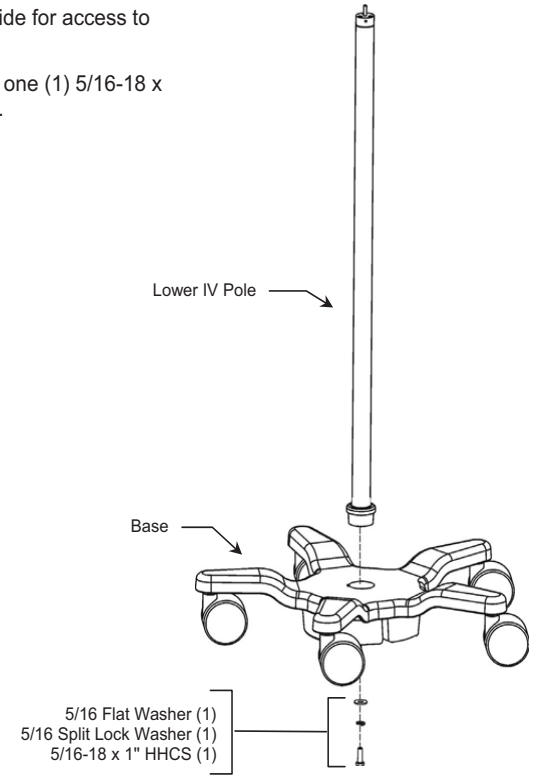


Tools Required

1/2" [13mm] wrench (not provided) 5/32" and 3/32" hex wrenches (provided).

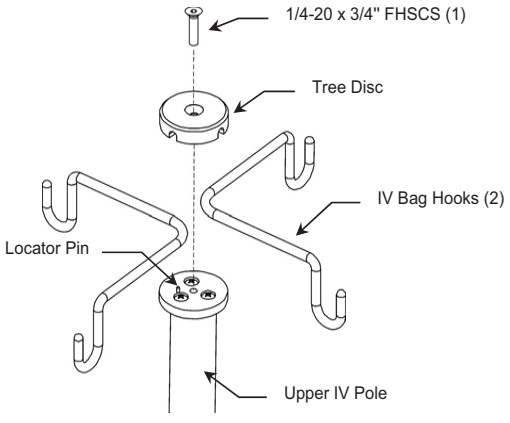
Assembling the Roll Stand (Post to Base)

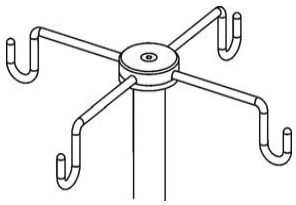
1. Insert Lower IV Pole in Base and lay assembly on its side for access to bottom of Base (not shown).
2. Using a 1/2" [13 mm] wrench, fasten Post to Base with one (1) 5/16-18 x 2" HHCS, 5/16 split lock washer, and 5/16" flat washer.



Attaching IV Bag Hooks to Upper IV Pole

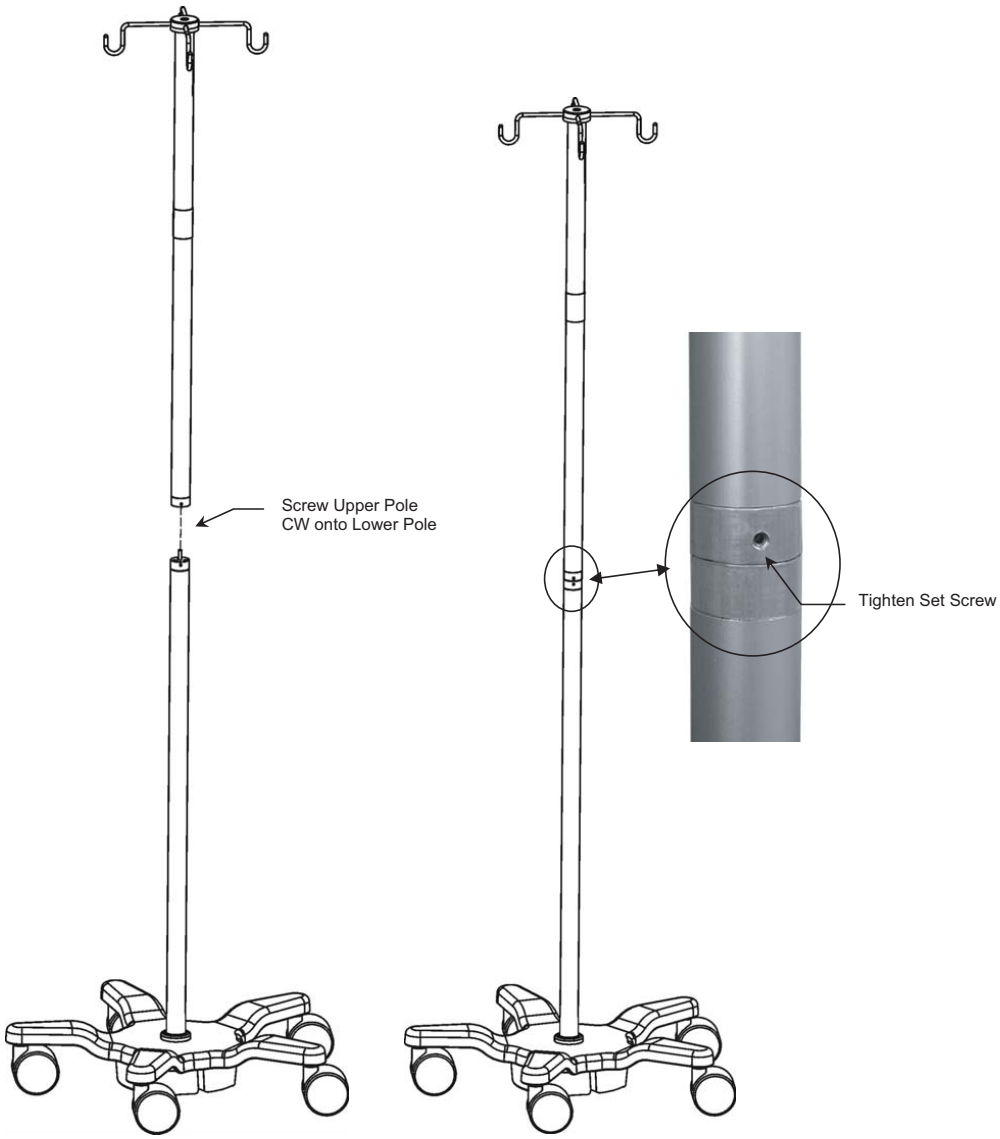
1. Assemble Tree Disc over IV Bag Hooks. Installation Note: If IV Bag Hooks do not fit easily into Tree Disc slots, gently tap Hooks into slots with a rubber mallet.
2. Align locator pin (top of Pole) with slot in Tree Disc. Using the 5/32" hex wrench provided, fasten assembly to top of Upper IV Pole with one (1) 1/4-20 x 3/4" FHSCS (1) as shown below.





Attaching Upper IV Pole to Lower Pole

1. Screw Upper Pole clockwise (CW) onto Lower Pole. Tighten as much as possible by hand.
2. Using the 3/32" hex wrench provided, tighten the set screw in the Upper Pole.



Routine Maintenance

Periodically check all mounting hardware. Tighten as necessary for optimal operation.

Cleaning the Mounting Assembly

1. The mounting assembly may be cleaned with most mild, non-abrasive solutions commonly used in the hospital environment (e.g. diluted bleach, ammonia, or alcohol solutions).
2. The surface finish will be permanently damaged by strong chemicals and solvents such as acetone and trichloroethylene.
3. Do not use steel wool or other abrasive material to clean the mounting assembly.
4. Damage caused by the use of unapproved substances or processes will not be covered by warranty. We recommended that you test any cleaning solution on a small area of the mounting assembly that is not visible to verify compatibility.
5. Never submerge the roll stand or allow liquids to enter the mounting assemblies Wipe any cleaning agents off the mounting assembly immediately, using a water-dampened cloth. Dry all mounting assemblies thoroughly after cleaning.

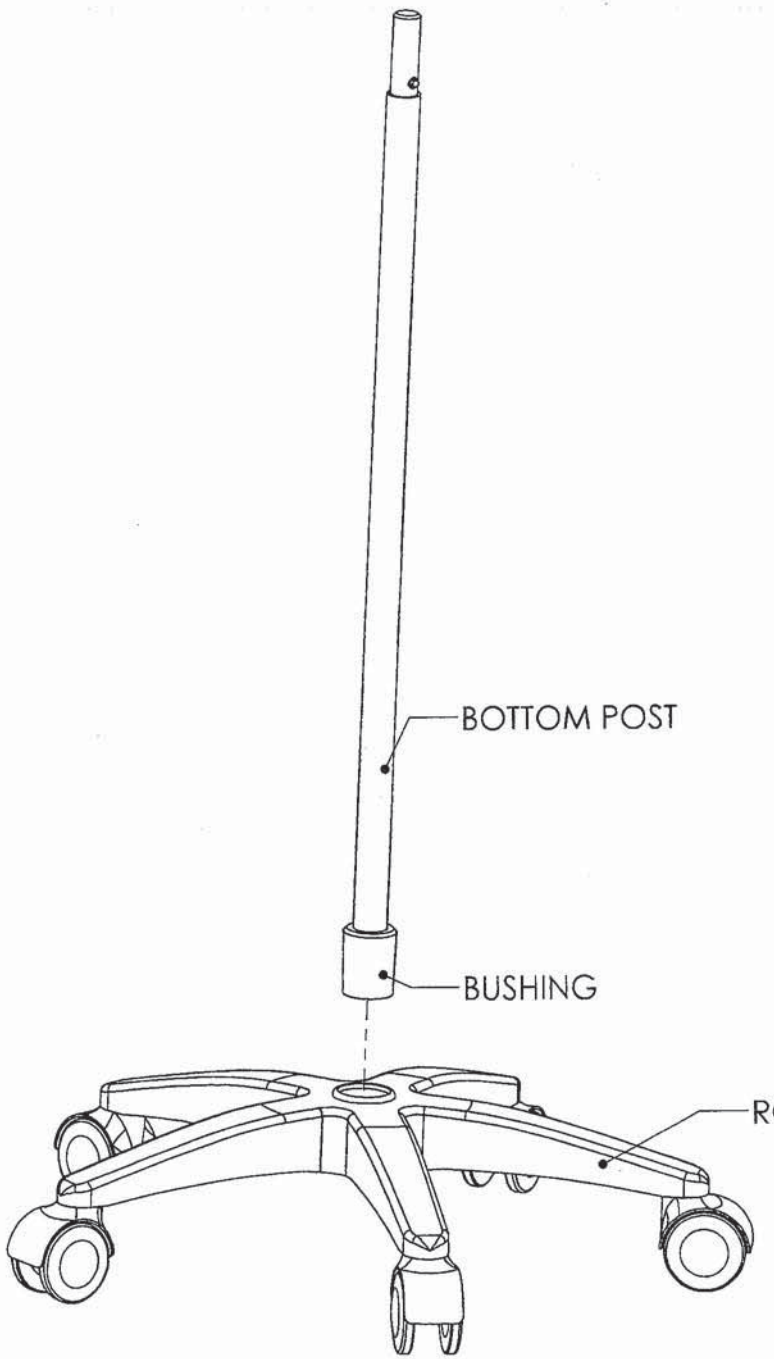
CAUTION: GCX makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection. Consult your hospital's infection control officer or epidemiologist. To clean or sterilize mounted instruments or accessory equipment, refer to the specific instructions delivered with those products.

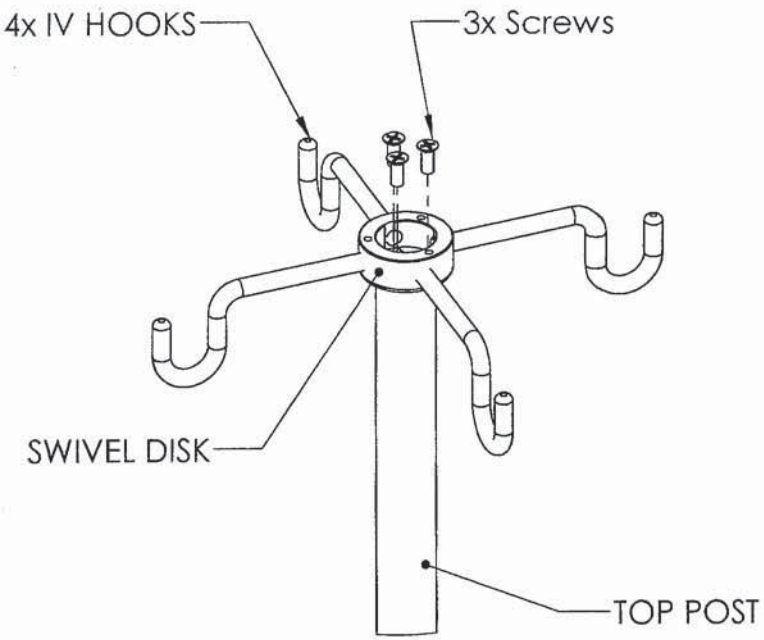
IV POLE CONFIGURATION 2

1119 I.V. POLE ASSEMBLIES AND PARTS DESCRIPTIONS

NOTE: The following tools are required for the assembly of this IV Pole:

Small Screws	1/8” HEX
Big Screws	3/16” HEX
Bolthead	1/2” Wrench





STEP2: *SCREW THE HOOKS INTO THE SWIVEL PIECE, SECURE THE SWIVEL TO THE TOP POST USING THE 3x FLAT-HEAD SCREWS PROVIDED. NOTE THAT THE TRI-HOLE PATTERN IS ASSYMETRICAL, AND THEREBY ONLY ONE CORRECT HOLE-ALIGNEMENT CONFIGURATION IS POSSIBBLE.*

STEP1: *ASSEMBLE THE BOTTOM POST+ BUSHING ASSEMBLY ONTO THE ROLLSTAND BASE*

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85 Fulton Way
Richmond Hill, Ontario
L4B 2N4, CANADA
Tel: (905)763-7778
Fax: (905)763-8587

DESCRIPTION: IRADIMED CUSTOMER MANUAL

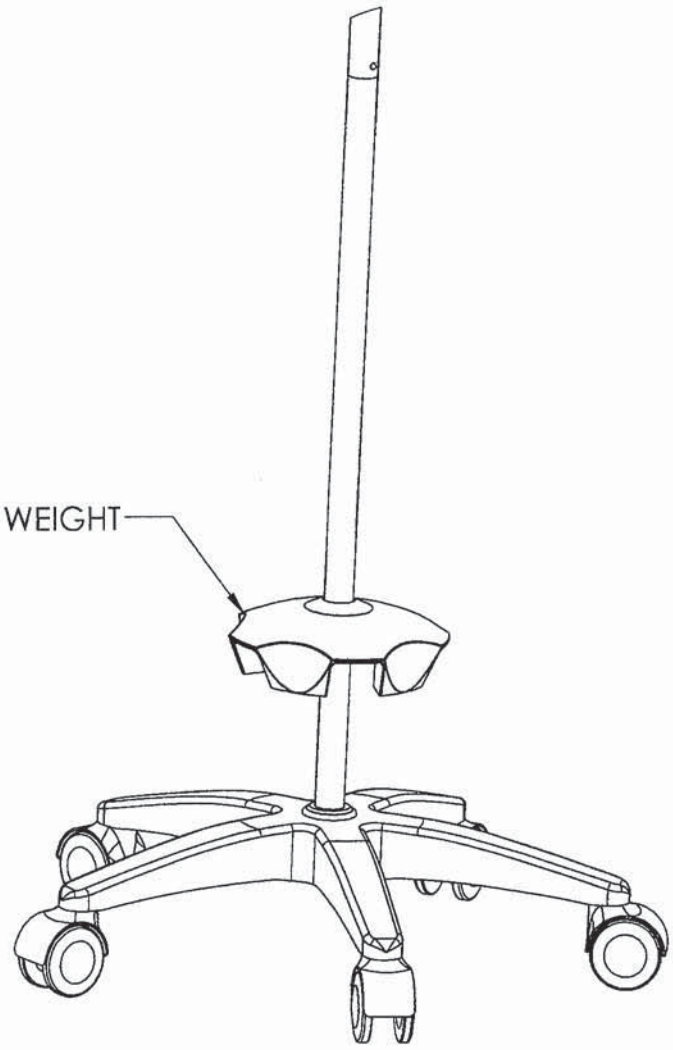
PART NO: STEP 1 & 2

SCALE: NTS | SHT. - OF -

DRAWN BY: FO | DATE: MAR/19/210

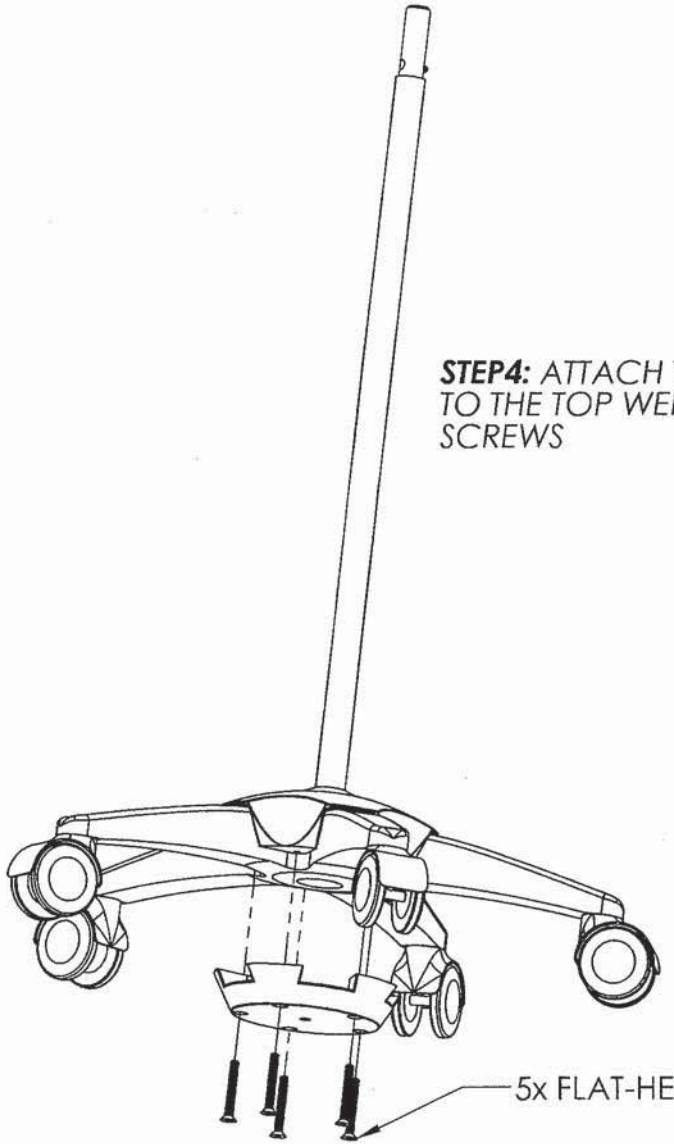
CHECKED BY: - | DATE: ~

DRAWING NO: 100319-F01



STEP3: *SLIDE THE TOP WEIGHT ON THE POST AND REST IT ON BASE ASSEMBLY*

STEP4: *ATTACH THE BOTTOM WEIGHT TO THE TOP WEIGHT USING 5X FLAT-HEAD SCREWS*



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DESCRIPTION: IRADIMED CUSTOMER MANUAL

PART NO: STEP 3 & 4

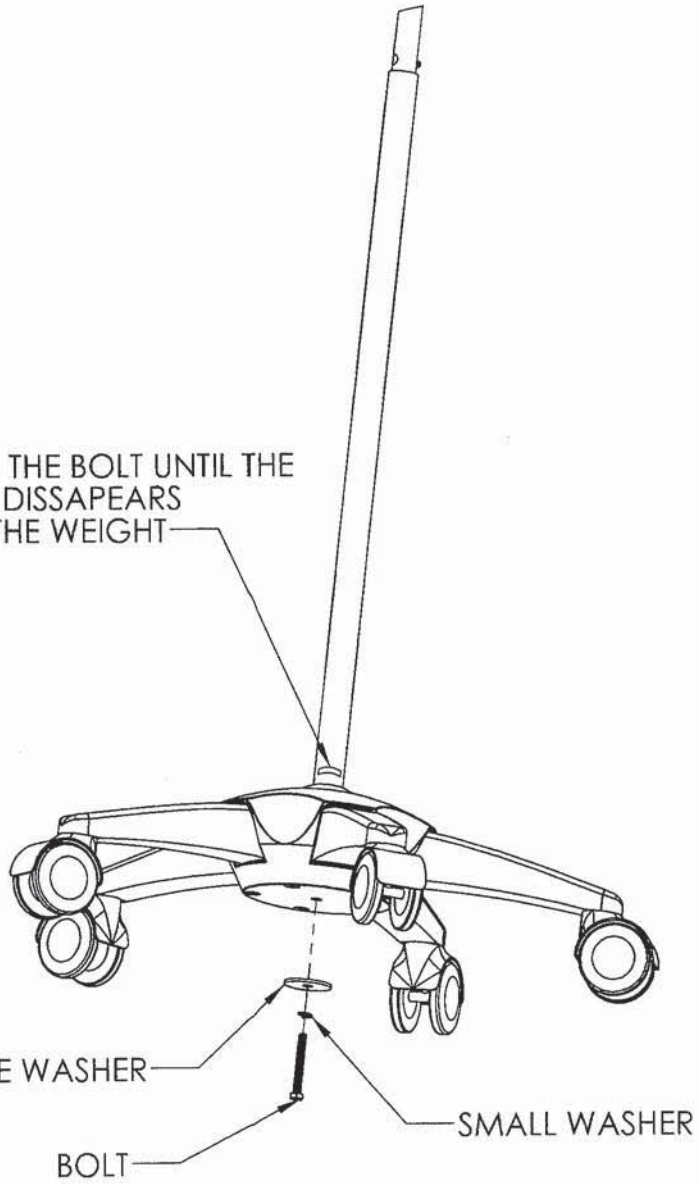
SCALE: NTS | SHT. ~ OF ~

DRAWN BY: FO | DATE: MAR/19/210

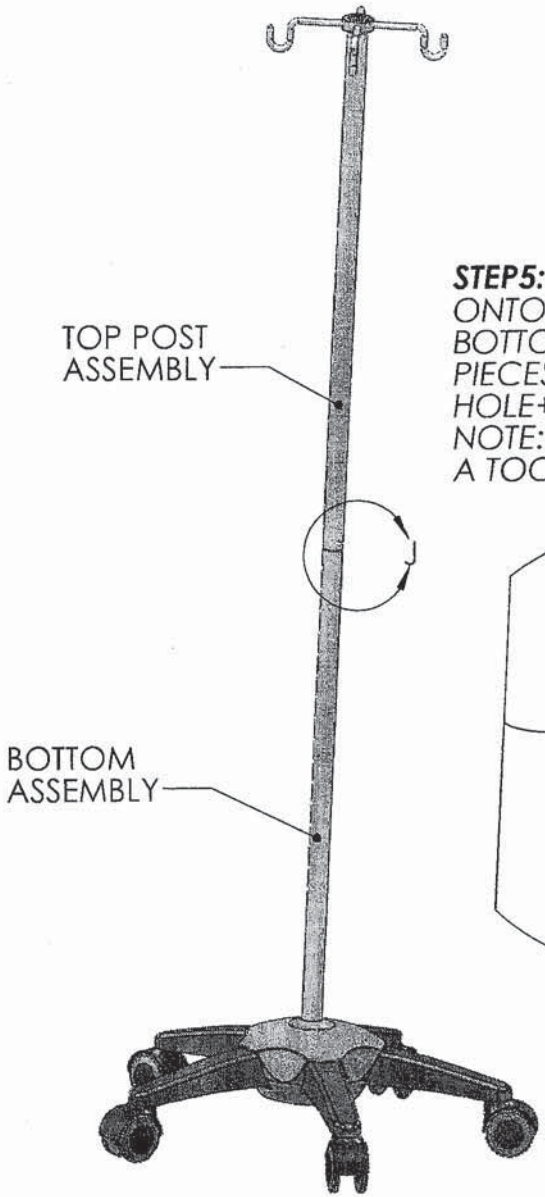
CHECKED BY: ~ | DATE: ~

DRAWING NO: 100319-F01

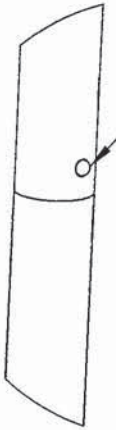
NOTE:
TIGHTEN THE BOLT UNTIL THE STICKER DISSAPEARS UNDER THE WEIGHT



STEP5: *SECURE THE POST ASSEMBLY TO THE WEIGHT ASSEMBLY USING THE LARGE AND SMALL WASHER AND THE BOLT, IN THE SEQUENCE SHOWN IN THE ASSEMBLY*



STEP5: *SLIDE THE TOP POST ASSEMBLY ONTO THE CONNECTOR OF THE BOTTOM ASSEMBLY AND LOCK THE PIECES TOGETHER USING THE HOLE+PLUNGER MECHANISM*
NOTE: PUSH THE PLUNGER PIN WITH A TOOL



PLUNGER PIN
(ENSURE TIP OF PLUNGER IS PROTRUDING FROM THE POST)

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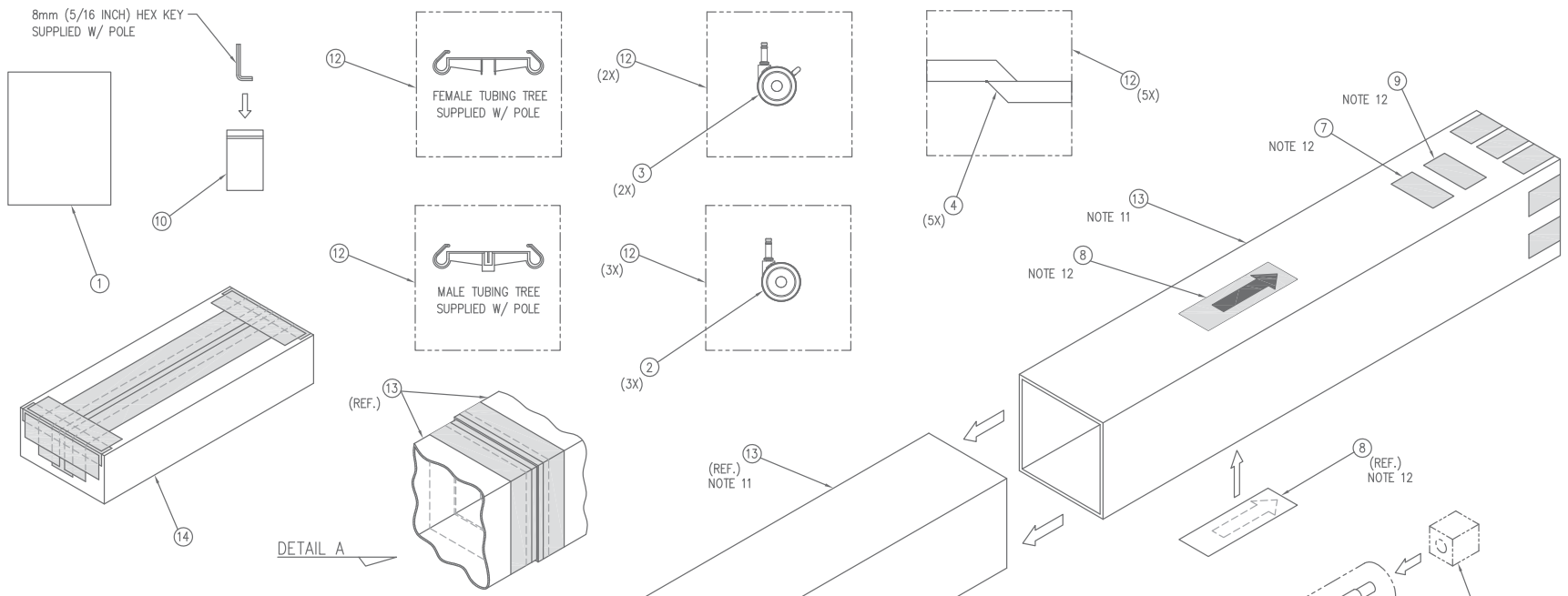
DESCRIPTION: IRADIMED CUSTOMER MANUAL
PART NO: STEP 5 & 6
SCALE: NTS
DRAWN BY: FO
DATE: MAR/19/210
CHECKED BY: -
DATE: -
SHT. - OF -
DRAWING NO: 100319-F01



ASSEMBLY NOTES:

1. THE POLE BASE IS SUPPLIED WITH A LAYER OF BUBBLE WRAP. ADD A DOUBLE SECTION OF M064 BUBBLE WRAP, (ITEM 11) FOR ADDITIONAL PROTECTION. SECURE IN PLACE W/ PACKING TAPE.
2. THE POLE COUPLING W/ LEVER IS ALSO SUPPLIED COVERED WITH A PROTECTIVE PLASTIC SLEEVE. SLIDE THE SLEEVE DOWN. UNSCREW THE LEVER AND PLACE IT INTO A ZIPLOCK BAG M022, (ITEM 10). PLACE BAGGED LEVER INTO BOX M071, (ITEM 14) AFTER LEGS AND CASTERS, (SEE NOTE 6), HAVE BEEN PLACED INTO THE BOX. PRINT LOT NUMBER ONTO LABEL LB2009, (ITEM 6) AND ATTACH TO POLE UNDER THE COUPLING AS SHOWN. SLIDE PROTECTIVE SLEEVE BACK UP AND SECURE IN PLACE W/ PACKING TAPE IF NECESSARY.
3. CUT A PIECE OF SPARE FOAM PACKING MATERIAL SUCH AS M005 OR M016 INTO A 2.00 X 2.00 X 2.00 CUBE. CUT A ø0.38–0.50 HOLE APRX. HALF–WAY INTO THE CUBE ON ONE SIDE. PLACE CUBE ON TOP END OF POLE. HOLD IN PLACE W/ PACKING TAPE IF NECESSARY.
4. WRAP 5 LEGS HM106, (ITEM 4) W/ 1 PIECE EACH OF M065, (ITEM 12) AND SECURE W/ PACKING TAPE.
5. WRAP 3 PLAIN CASTERS HM104, (ITEM 2) AND 2 LOCKING CASTERS HM105, (ITEM 3) INDIVIDUALLY W/ 1 PIECE EACH OF M065, (ITEM 12) AND SECURE W/ PACKING TAPE.
6. PLACE 5 WRAPPED LEGS AND 5 WRAPPED CASTERS INTO BOX M071, (ITEM 14). ARRANGE THEM IN A WAY SO THAT THERE IS MINIMUM PRESSURE OF ONE PART AGAINST ANOTHER.
7. WRAP 1 MALE AND 1 FEMALE TUBING TREE, (SUPPLIED W/ POLE) W/ 1 PIECE EACH OF M065, (ITEM 12) AND SECURE W/ PACKING TAPE. PLACE INTO BOX M071, (ITEM 10) ON TOP OF LEGS.
8. PLACE 8mm (5/16 INCH) HEX KEY, (SUPPLIED W/ POLE) INTO ZIPLOCK BAG M022, (ITEM 15) AND PLACE INTO BOX M071, (ITEM 14) ON TOP OF LEGS.
9. PLACE INSTALLATION GUIDE 1179, (ITEM 1) INTO BOX M071, (ITEM 14). SEAL BOX W/ PACKING TAPE; 3 STRIPS ACROSS LENGTHWISE SEAM, OVER AND DOWN ENDS (1 IN CENTER, 1 EACH ON SIDES TO HOLD CENTER STRIP). SEAL ENDS OF BOX IN A SIMILAR FASHION PLACING TAPE ON TOP OF LENGTHWISE TAPE.
10. SEAL THE ENDS OF BOTH SECTIONS OF THE TELESCOPING BOX M070, (ITEM 13) W/ PACKING TAPE. USE 2 PIECES TO CLOSE THE FLAP AND THEN 3 PIECES IN THE OPPOSITE DIRECTION FOR ADDITIONAL SECURITY.
11. PLACE POLE HM107, (ITEM 5) INTO BOTTOM (SMALLER) SECTION OF THE TELESCOPING BOX M070, (ITEM 13) WITH THE BASE FACING DOWN. ADD THE COMPLETED BOX M071, (ITEM 14) BY SLIDING DOWN ALONGSIDE THE POLE. PLACE THE TOP (LARGER) SECTION OF THE TELESCOPING BOX OVER THE BOTTOM SECTION UNTIL IT TOUCHES THE TOP OF THE POLE. SEAL THE BOX BY WRAPPING 3 PIECES OF PACKING TAPE AROUND THE SEAM; THE FIRST PIECE OVER THE SEAM AND THE OTHER TWO PIECES ON EACH SIDE. SEE DETAIL A.
12. ATTACH LABELS LB2056, (ITEM 9) W/ LOT NUMBER, LB2019A, (ITEM 7), AND LB2055, (ITEM 8) TO TALL BOX M070, (ITEM 13) AS SHOWN. ALL LABELS ARE PRINTED BY ENGINEERING / DOC. CONTROL.

NON-MAGNETIC PART

SEE ELECTRONIC B.O.M. 1119

Rev.	Description	Date
D	ECN 000471	29MAY15
C	ECN 000229	07DEC07
B	ECN 000149	19JAN07
A	ECN 000081	22MAY05

Revision History

Tolerances unless otherwise noted on dwg.: .XX = ± .02, .XXX = ± .010, ∠ = ± 1°

Drawn: GRB Date: 01JUN05
Eng: JRN Date: 07DEC07
QA: FXC Date: 07DEC07
MFG: TWF Date: 07DEC07

Do NOT scale this drawing !

Third Angle Projection

Tradimed Corporation

Title: ROLL STAND, NON–MAGNETIC

Size: D

Part/Dwg. No: 1119

Rev: D

Cad. Scale: NONE

Sheet 1 of 1

LF20 Rev. A

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APPENDIX H
TRUMPET AND START UP CURVES

In this Pump, as with all infusion systems, the actions of the pumping mechanism can cause short term fluctuations in rate accuracy. The graphs below (Figure G-1 through G-14) show typical performance of the system with its specific infusion sets.

For those not familiar with trumpet curves, the “0” line in each Figure represents the set flow for the pump and quantities above this line represent the percentage by which the delivered flow exceeds the set flow rate. Quantities below the line represent a flow rate that delivers less than the set flow rate. The heavy, dark solid line represents the average flow rate error for the entire test interval, typically less than 3%.

The maximum positive and negative mean flow errors are shown at 2, 5, 11, 19, and 31 minute averages, and the trumpet curves interpolate the data between these points. The longer the time interval is, the narrower the error range will be. For example, an interval of 15 minute will show a narrower error range than an interval of 3 minute. This is because, at longer observation intervals, fluctuations — even large ones — occurring for only a few minutes represent a comparatively small portion of the data points being analyzed. Conversely, for a shorter interval, any fluctuation will have greater weight.

Because of this weighting, the plotted curve takes on its trumpet shape, with the bell of the trumpet widening at the shorter observation periods. For further information refer to Health Devices Vol. 27 Nos. 4-5 (April-May 1998).

As detailed in the product standards listed below, trumpet curves are named for their characteristic shape. They display discrete accuracy data averaged over particular time periods or “observation windows”, not continuous data versus operating time. Over long observation windows, short-term fluctuations have little effect on accuracy, as represented by the flat part of the curve. Variations in system accuracy and start up characteristics over various observation windows can be of interest when certain drugs are being delivered. Trumpet curves are all derived from the second hour of the data collection period.

FLOW CHARACTERISTICS UNDER VARYING DELIVERY CONDITIONS

Effects of Pressure Variations

Under conditions of +300 mmHg pressure, the MRidium™ 3860 Infusion System exhibits a long-term accuracy offset of approximately -1.0% from mean values. Under conditions of -100 mmHg pressure, the MRidium™ 3860 Infusion System exhibits a long-term accuracy offset of approximately +3.0% from mean values. No significant change in short–term variations result under these pressure conditions.

Effects of Negative Solution Container Heights

With a negative head height of -0.5 meters, the MRidium™ 3860 Infusion System exhibits a long–term accuracy offset of approximately -2.0% from mean values. No significant change in short–term variations result under negative head height conditions.

Effects of Rate

No significant change in short–term variations result with rates of 1.0 ml/hr or above.

NOTE: Tests were conducted in accordance with IEC 60601–2–24, "Particular requirements for safety of infusion pumps and controllers" and AAMI ID26–1998 "Medical electrical equipment - Part 2: Particular requirements for the safety of infusion pumps and controllers." MRidium 1056 Infusion Sets were used during this testing.

Occlusion Pressure Tests

NOTE: 2 PSI = 13.8 kPa, 10 PSI = 68.8 kPa

Occlusion Pressure Test Conditions	**Occlusion Pressure Test Results**
Occlusion Detection Time: Pressure limit at 2 PSI, Flow Rate at 1 mL/hr	8 minutes (2 PSI setting), 55:00 minutes (10 PSI setting)
Occlusion Detection Time: Pressure limit at 10 PSI, Flow Rate at 25 mL/hr	8 minutes (2 PSI setting), 108 seconds (1:48 minutes at 10 PSI setting), max pressure reached was 10.2 PSI
Occlusion Detection Time: Pressure limit at 10 PSI, Flow Rate at 100 mL/hr	26 seconds (10 PSI setting), max pressure reached was 10.1 PSI
Occlusion Detection Time: Pressure limit at 10 PSI, Flow Rate at 500 mL/hr	8 seconds (10 PSI setting), max pressure reached was 9.9 PSI
Occlusion Detection Time: Pressure limit at 10 PSI, Flow Rate at 999 mL/hr	8 seconds (10 PSI setting), max pressure reached was 10.8 PSI
Post-Occlusion Pressure Alarm: Occlusion Relief Bolus Volume Delivered - Pressure limit at 2 PSI, Flow Rate at 25 mL/hr	Measured value was <0.7 mL after bolus release
Post-Occlusion Pressure Alarm: Occlusion Relief Bolus Volume Delivered - Pressure limit at 10 PSI, Flow Rate at 25 mL/hr	Measured value was 0.7 mL after bolus release
Battery Operating Time: Flow Rate at 25mL/hr (typical)	> 12 Hours at 25mL/hr Rate

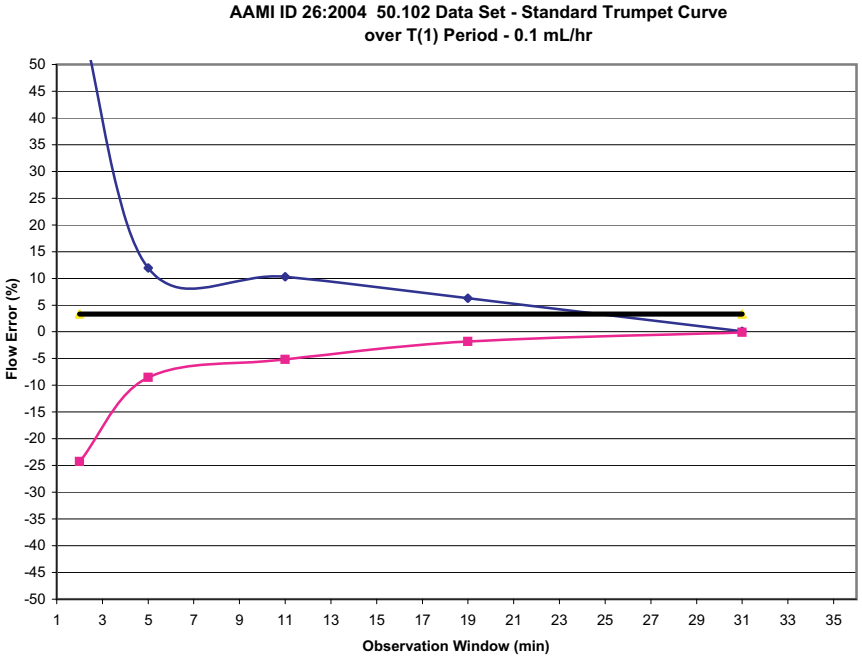
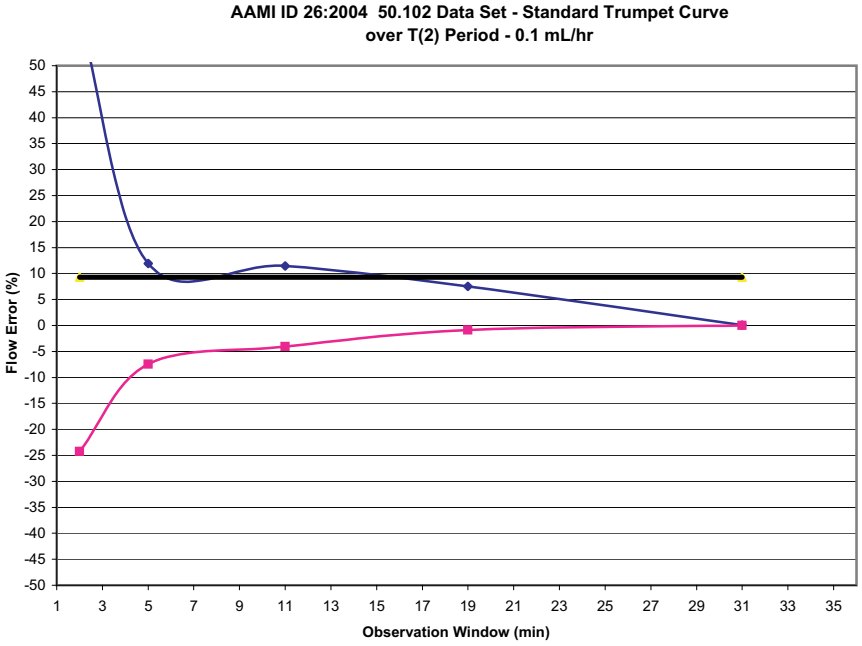


Figure H-1.



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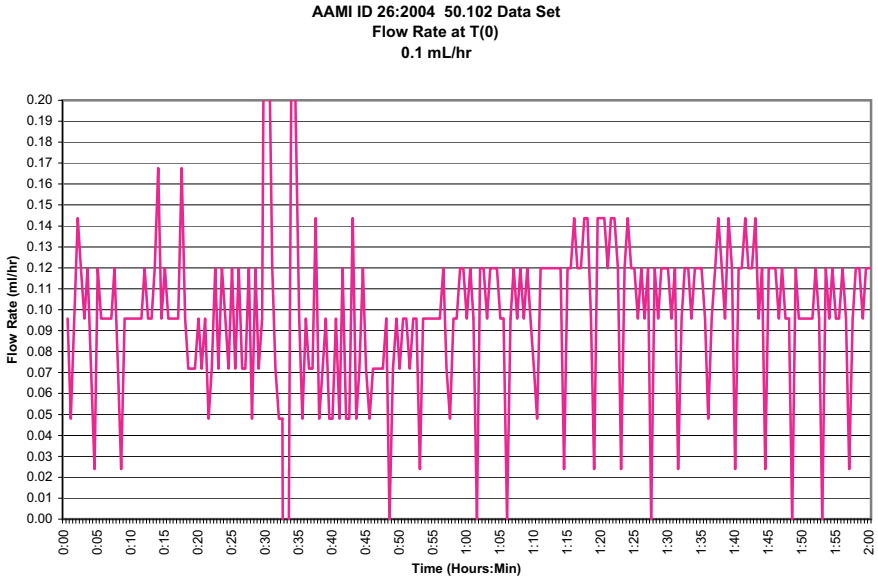

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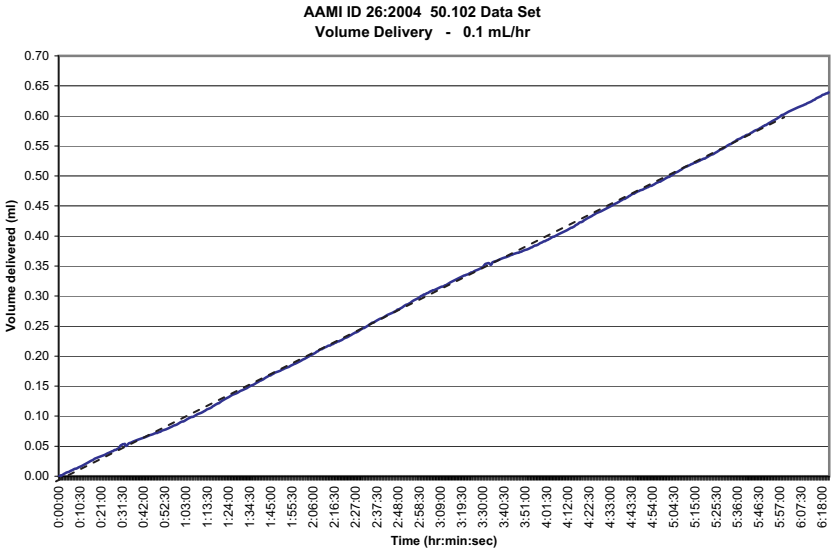

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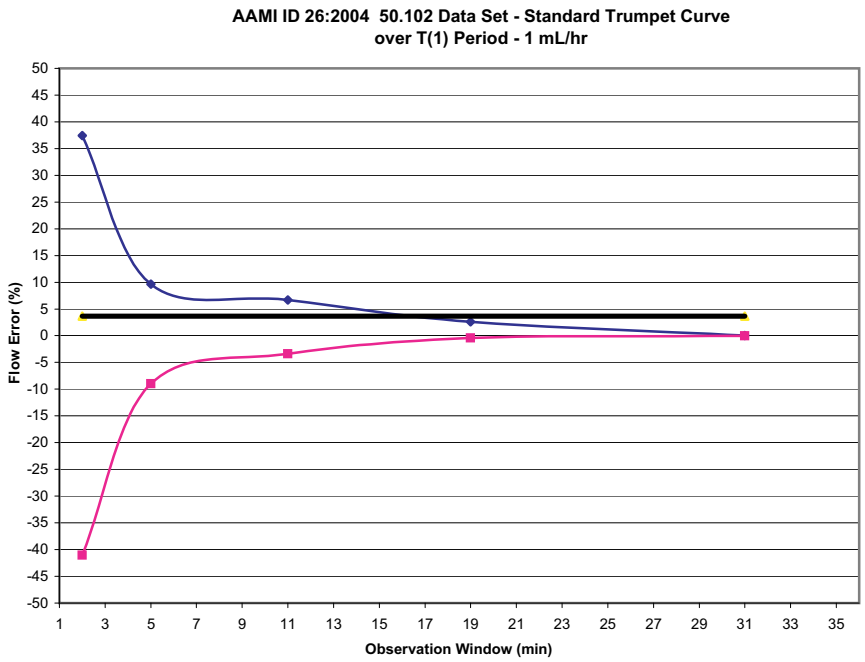

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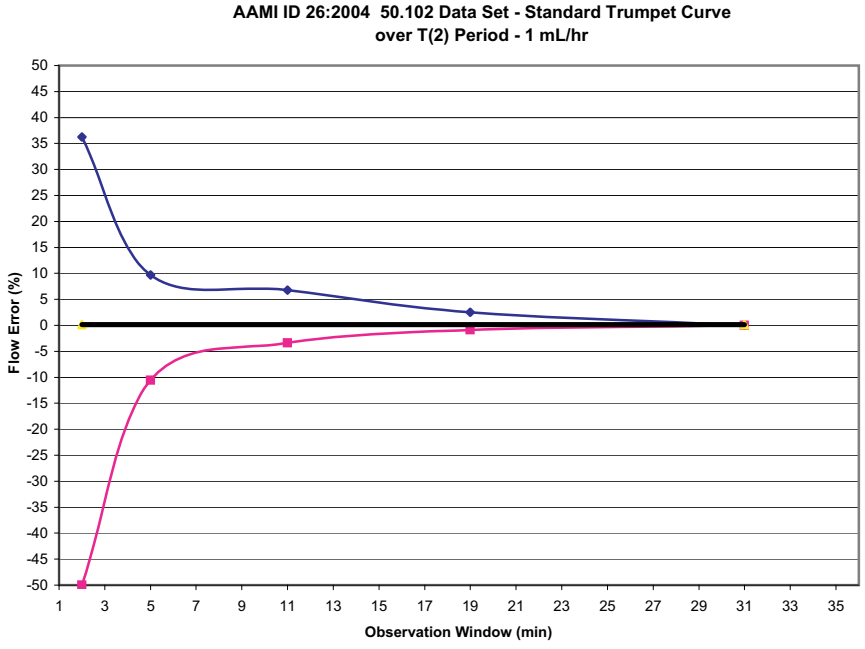

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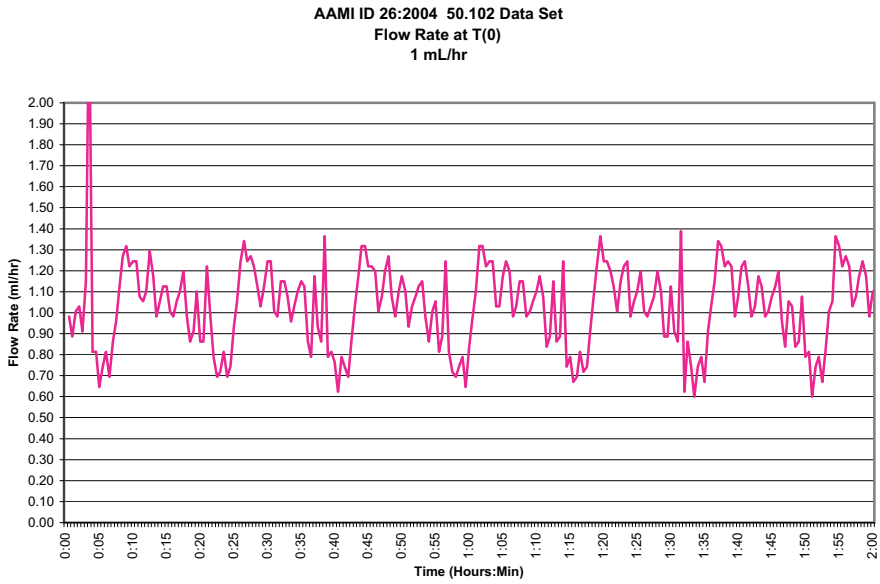

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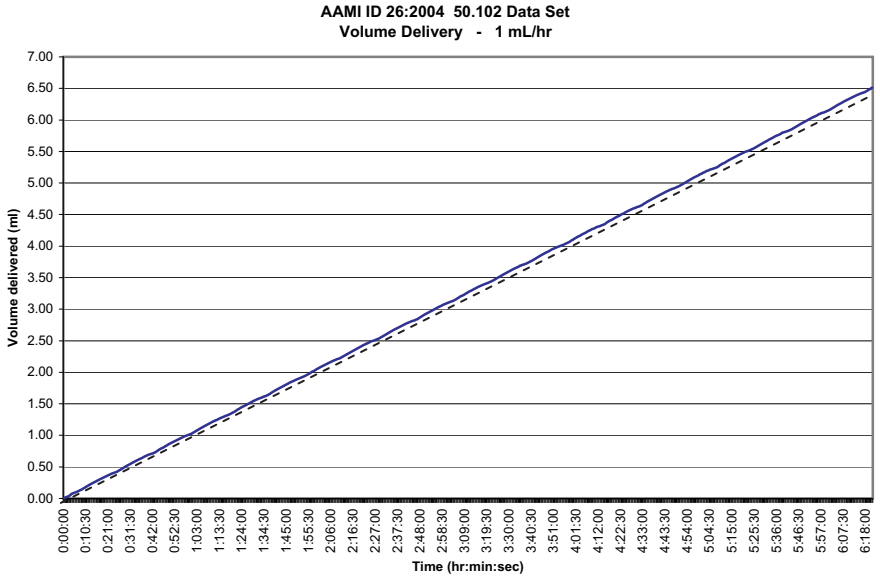

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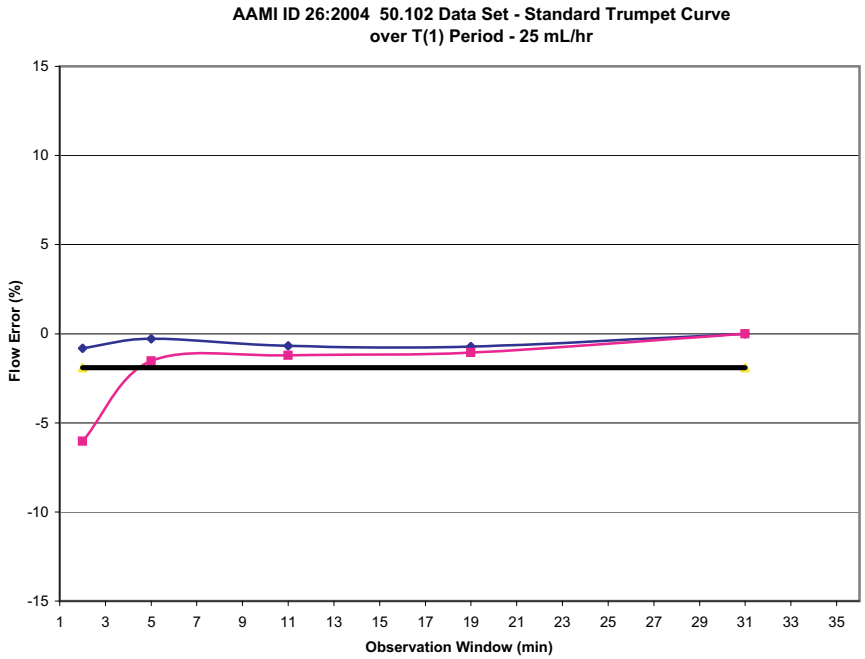

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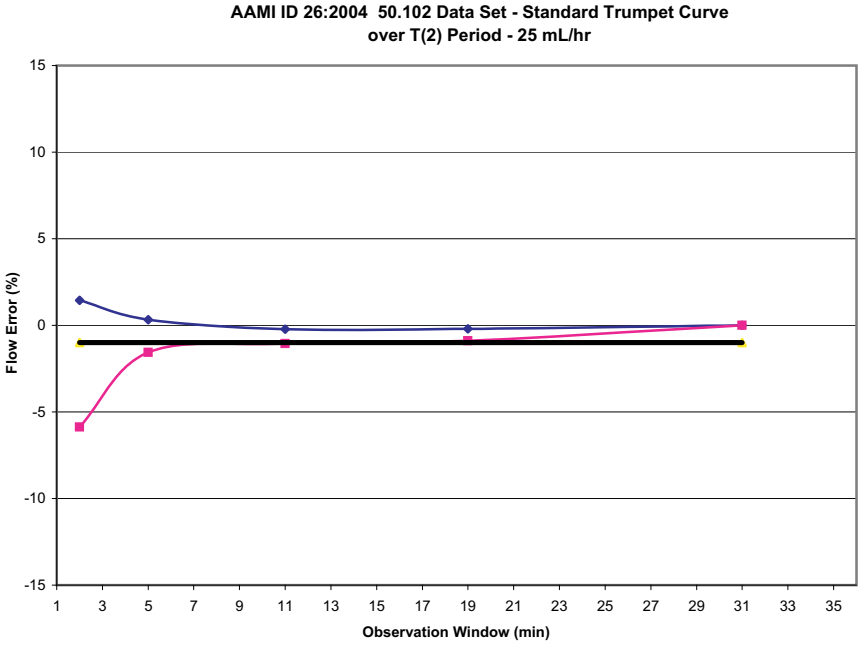

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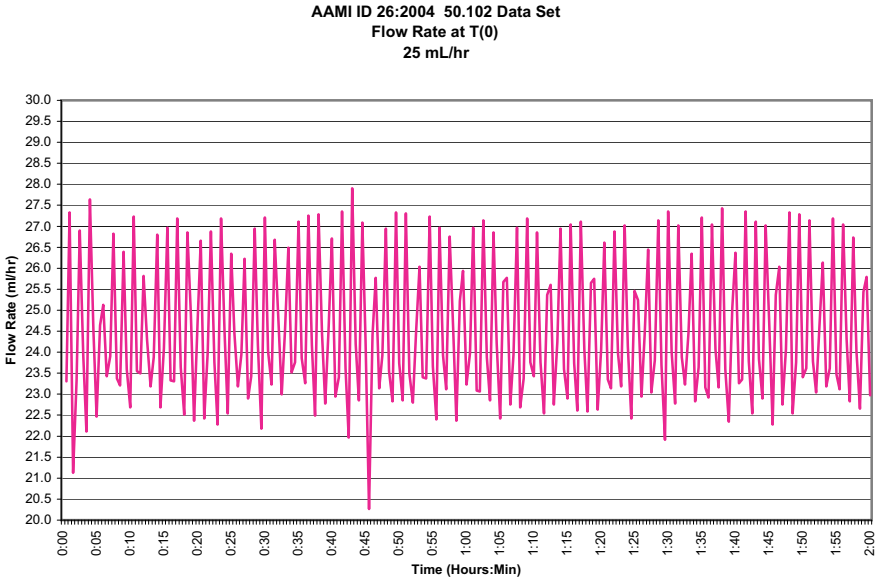

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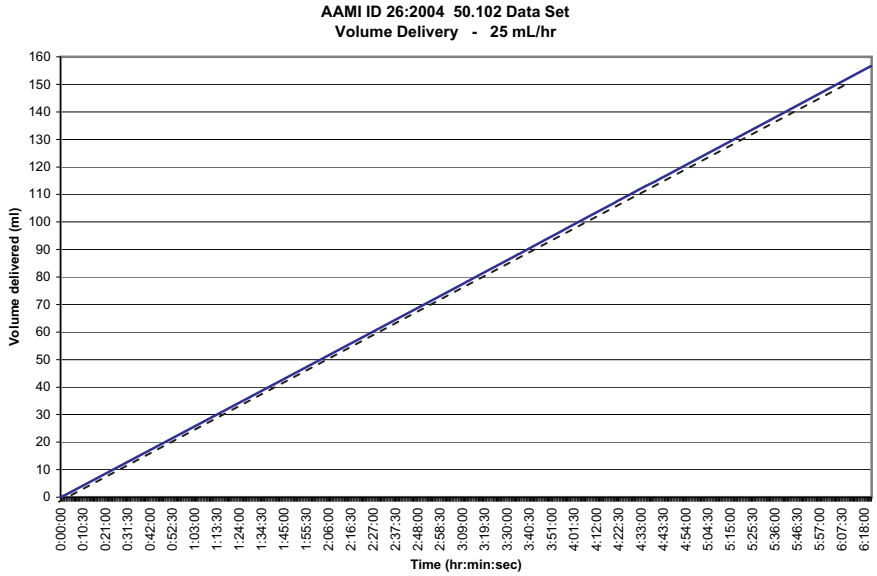

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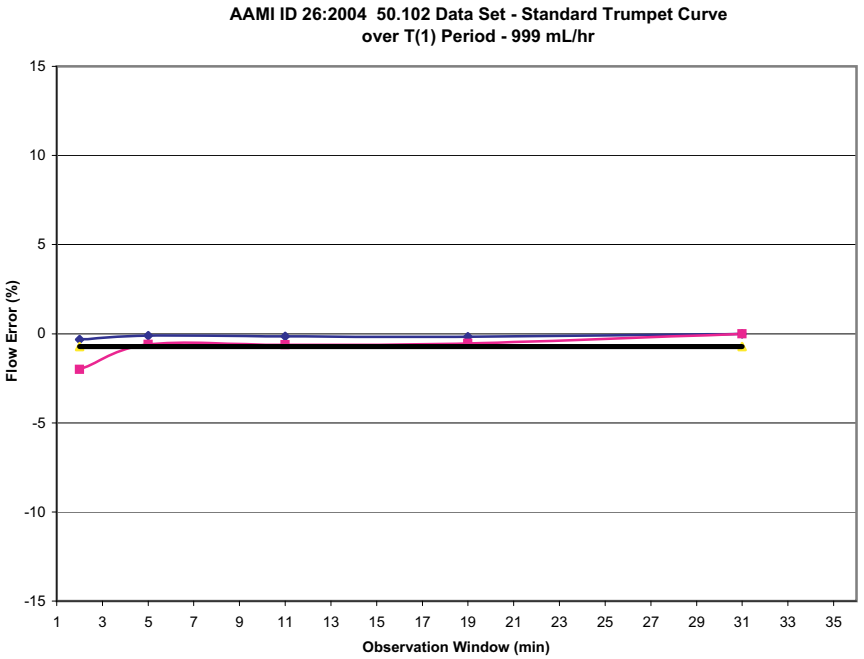

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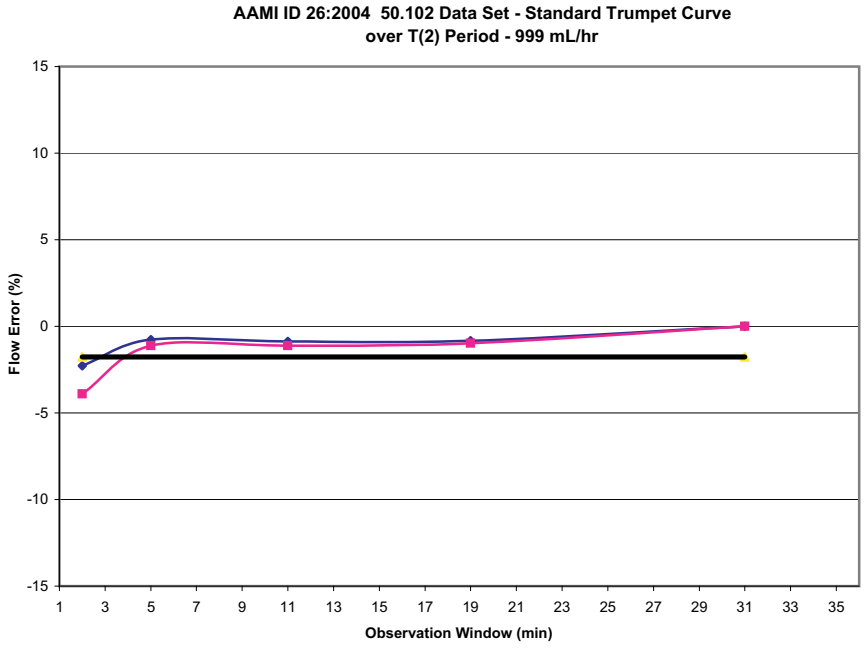

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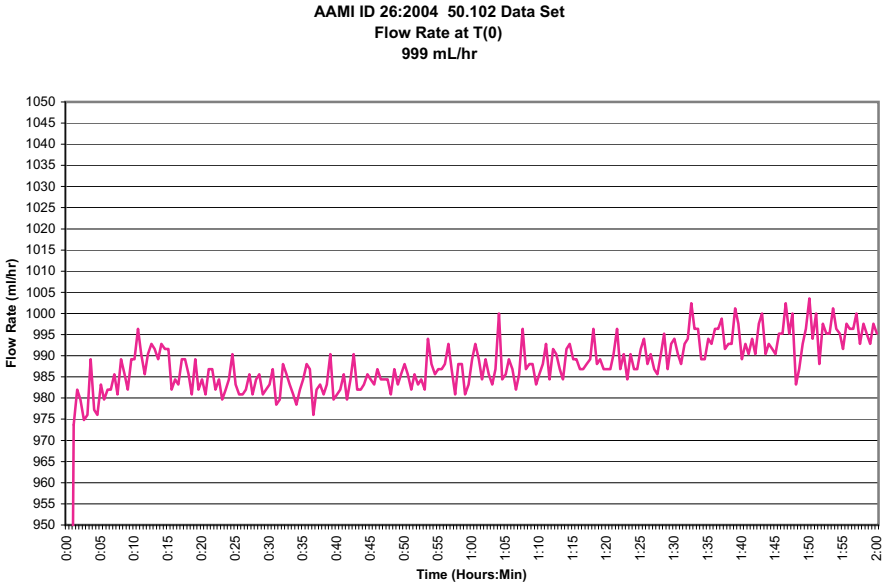

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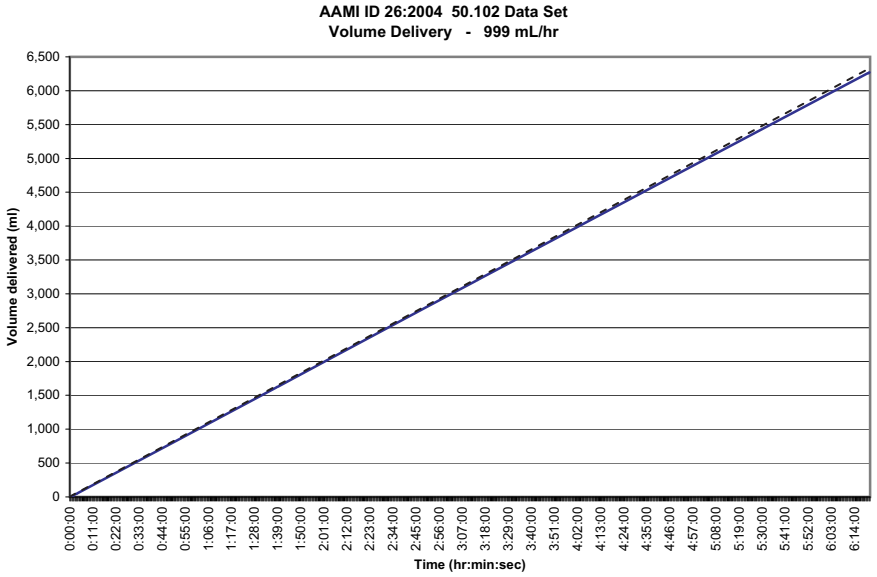

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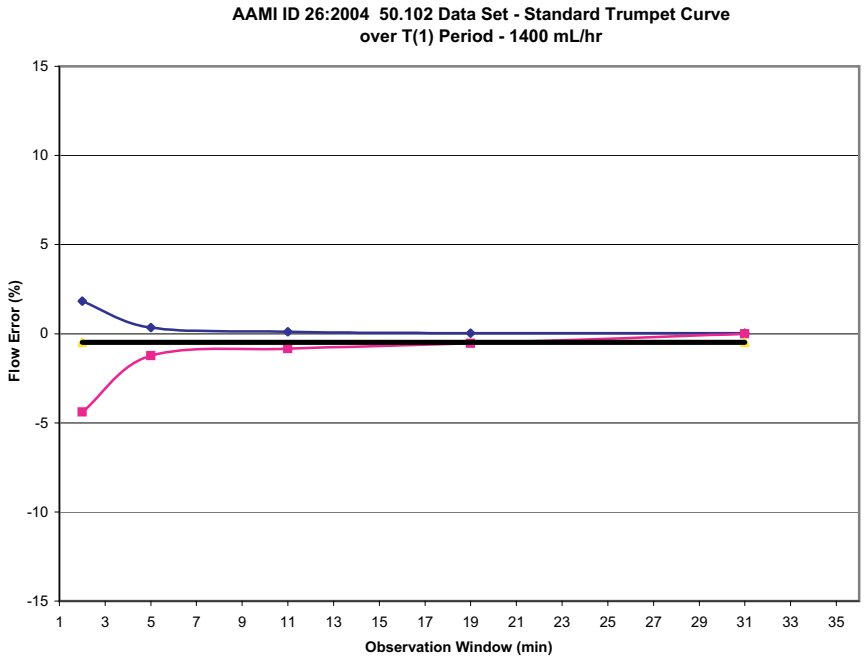

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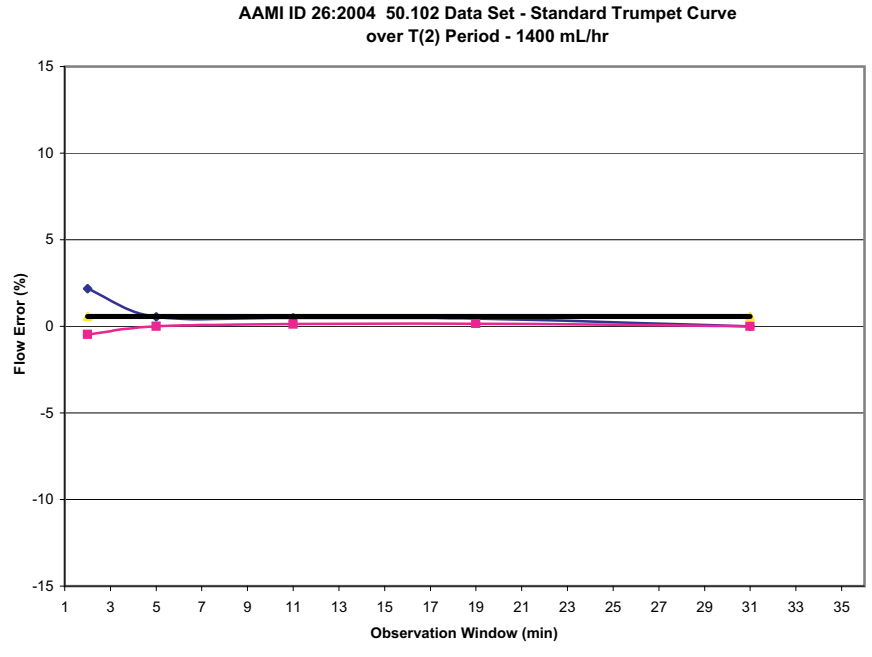

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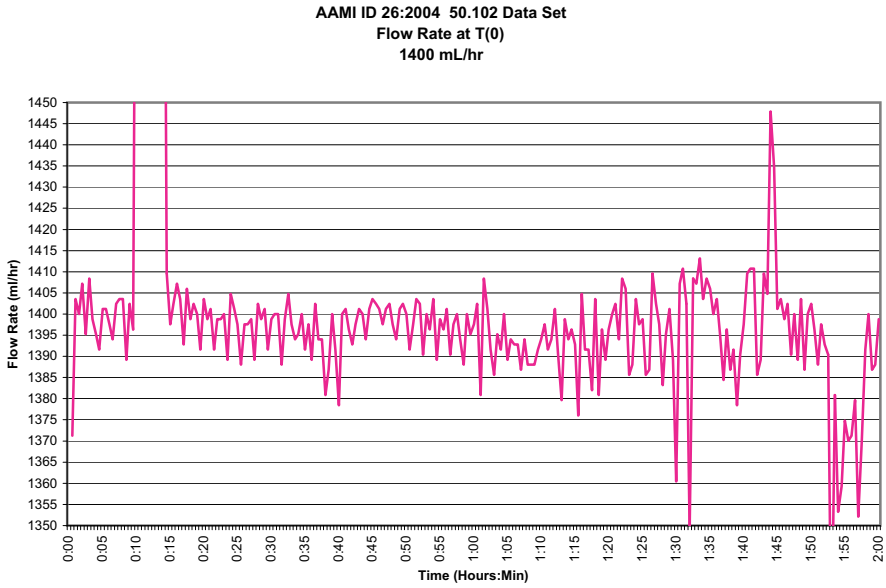

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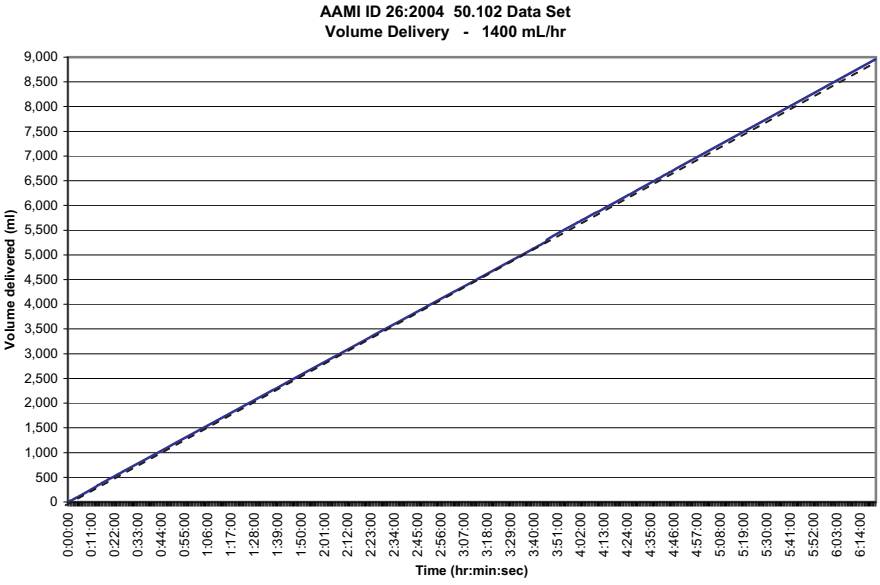

Figure H-20.

NOTES